

**THE MEASUREMENT OF THREATS TO PATIENT SAFETY IN
AUSTRALIAN GENERAL PRACTICE**

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*To John,
Charles, Georgina and Eloise*

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LIST OF ABBREVIATIONS

AAFP	American Academy of Family Physicians
ACSQHC	Australian Commission for Safety and Quality in Health Care
ASIPS	Applied Strategies for Improving Patient Safety
ATSI	Aboriginal and Torres Strait Islander peoples
DOHA	Department of Health and Aging of the Commonwealth of Australia
GP(s)	General practitioner(s)
HMPS	Harvard Medical Practice study
ICPC	International Classification of Primary Care
ISP	Internet Service Provider
JCAHO	Joint Commission on Accreditation of Healthcare Organisations
NESB	Non-English speaking background
NHS	National Health Service
NOS	Not otherwise specified
NPSA	National Patient Safety Agency
NSW	New South Wales
PCISME	The Primary Care International Study of Medical Error
PIN(s)	Personal identification number(s)
QACE	Quality Assurance and Continuing Education
QAHCS	Quality in Australian Health Care study
RACGP	Royal Australian College of General Practitioners
RRMA	Rural, Remote and Metropolitan Area classification
RM	Risk management
SLA	Service Level Agreement
TAPS	Threats to Australian Patient Safety
UK	United Kingdom
US	United States
WHO	World Health Organisation

Declaration

This thesis is submitted to the University of Sydney in fulfilment of the requirements for the degree of Doctor of Philosophy. The work presented in this thesis is, to the best of my knowledge and belief, original and has not been published or written by another person, except where due reference is made in the text of the thesis. I hereby declare that I have not submitted this material, either in full or part, for a degree at this or any other institution. Parts of this thesis have been published in abstract form or as full papers and they are listed on page *iii*.

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Publications arising from this research

Peer reviewed scientific research papers

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(see Appendix 6)

Makeham MAB, Stromer S, Bridges-Webb C, Mira M, Saltman DC, Cooper C and Kidd MR. Patient safety events reported in general practice: a taxonomy. *Quality and Safety in Health Care*. IN PRESS, Accepted for publication June 15th 2007

(see Appendix 7)

Invited papers

Makeham MAB, Dovey S, Kidd MR. What we know: Monitoring threats to patient safety in community settings: a review of the literature.

www.saferhealthcare.org.uk (Peer reviewed website of the British Medical Journal/ National Patient Safety Agency, UK). IN PRESS, Accepted for publication June 15th 2007.

(see Appendix 8)

Makeham MAB and Dovey S. Patient safety methods and measures used for research in community settings. (A literature review)

WHO World Alliance for Patient Safety. December 2006

Other publications

Makeham MAB, Kidd MR, Saltman DC, Card G. Letter to the editor: Meningococcal Vaccine. *Australian Family Physician* 2004 Sep;33(9):679 (*Appendix 9 of this thesis*)

Conference proceedings

Makeham MAB, Kidd MR , Mira M, Cooper C, Saltman D, Bridges-Webb C, Stromer S. Threats to Australian Patient Safety (TAPS) Project: determining the incidence of reported errors in general practice. Annual Scientific Convention of the Royal Australian College of General Practitioners, Brisbane. October 2006.

Makeham MAB, Kidd MR, Saltman D. Bridging the knowledge gaps in patient safety – the Threats to Australian Patient Safety (TAPS) Project. WONCA Europe Conference. Florence, August 2006.

Makeham MAB, Kidd MR , Mira M, Cooper C, Saltman D, Bridges-Webb C, Card G. The Threats to Australian Patient Safety (TAPS) Project: using IT to improve patient safety in general practice. National Health Information Summit, Melbourne, December 2004.

Makeham MAB, Kidd MR , Mira M, Cooper C, Saltman D, Bridges-Webb C, Card G. Quality Care in general practice: Preliminary Findings from the Threats to Australian Patient Safety (TAPS) Project. General Practice and Primary Health Care Research Conference (PHCRIS), Brisbane, June 2004: 49

Makeham MAB, Card G, Kidd MR, Saltman D. Using IM/IT Systems in general practice research: The Threats to Australian Patient Safety Project. The Alliance of NSW Divisions' 6th Annual Vital Links State Forum, Sydney, May 2004: 27

Makeham MAB, Bridges-Webb C, Card G, Kidd MR, Saltman D. The TAPS Study – Threats to Australian Patient Safety Presentation to The Linnaeus Collaboration, hosted by the Australian Primary Health Care Research Institute, Australian National University, November 2003.

Abstract

The importance of better understanding error and safety in the community setting is widely accepted, with recent calls to promote efforts and improve resources in this area of research (Jacobson, Elwyn et al. 2003). The measurement of patient safety events in primary care is a relatively under-researched area and it is well recognized that there are large gaps in the research describing patient safety in ambulatory settings (Hammons, Piland et al. 2003). Attitudes towards embracing safety event measurement have improved in recent years, however there remains a substantial amount of work to be done before common standards can be recommended, despite recent calls in the scientific literature for national and international systems (Runciman, Williamson et al. 2006).

This thesis describes the Threats to Australian Patient Safety (TAPS) study, which aimed to create a secure anonymous web-based error reporting system suited to the Australian general practice setting, and then describe and quantify the errors reported by a representative random sample of Australian general practitioners.

The study was made possible with the support of funding from a National Health and Medical Research Council project grant, and also gained support from NSW Health and the Commonwealth Department of Health and Aging in the form of granting qualified privilege and providing essential Medicare data under legal instrument.

The study methodology involved the development of a database management system which created an electronic method for managing and analysing a wide variety of

features related to large numbers of anonymously reported errors from Australian general practice. A representative random sample of 84 general practitioners (GPs) from New South Wales (NSW) participated in the study, with over 400 errors reported in a 12 month period.

The key messages arising from the TAPS study were:

- GPs embraced anonymous patient safety event reporting using a secure website, with the majority of study participants making reports
- New findings from this study on the incidence of reported error in general practice were published in the scientific literature, which will help guide the design of future error reporting systems
- A new taxonomy to describe reported error from GPs was developed as part of this study and published in the scientific literature, with the view of allowing future self-coding of reported patient safety events by GPs

The TAPS study presented the first calculations known worldwide of the incidence of reported error in a general practice setting using a representative random sample of general practitioners. It was found that if an anonymous, secure, web-based reporting system was provided, approximately 2 errors were reported by general practitioners per 1000 patients seen per year (Makeham, Kidd et al. 2006).

In addition, the study created a simple descriptive general practice based error taxonomy, entitled the TAPS taxonomy (see Appendix 10) (Makeham, Stromer et al. 2007), and was the first study to test the reproducibility of the application of such a

tool using a group of general practitioners. The TAPS taxonomy developed as part of this study was found to have a good level of inter-coder agreement.

With respect to the underlying causes of errors, the TAPS study found that the majority of reported patient safety events were errors related to the processes of health care (70%), rather than errors related to the knowledge and skills of health professionals (30%).

Most errors reported in the TAPS study had the direct involvement of a patient (93% of error reports). Overall the reporting general practitioners were very familiar with these patients, who were on average 52 years old, and more often female (56%).

Around one quarter of the errors reported was associated with patients being harmed. Reports containing events related to processes of health care were associated less with harm than those containing events related to the knowledge and skills of health professionals.

The patients in errors associated with patient harm reported in the TAPS study were on average older than patients in reports where no harm was known to have occurred (58 years versus 50 years respectively). There was no statistically significant difference found between these groups with respect to gender or ethnicity, including people from Non-English speaking backgrounds or Aboriginal and Torres Strait Islander (ATSI) peoples, although the association with the latter group approached statistical significance.

Cases of patient death were reported in 8 of 415 errors reported in the TAPS study (2%), and more often involved events relating to the knowledge and skills of health professionals than events relating to the processes of health care compared to reports not involving a known patient death.

In support of suggestions in the scientific literature about the importance of anonymity as a feature of an error reporting system, a feedback interview found that an anonymous reporting system was a factor which made participants more likely to report error events, with two thirds of participants agreeing that anonymity made them more likely to participate in reporting. The majority of participants found the reporting process easy to undertake, and took approximately 6 minutes to send a report.

The study provided a self directed learning educational activity for participating general practitioners that was approved for 30 group 1 Quality Assurance and Continuing Education points by the Royal Australian College of General Practitioners (RACGP).

An important practical outcome of the TAPS study was that it highlighted a systematic error relating to immunisation failures with meningococcal vaccines which was reported to relevant organisations including NSW Health, the RACGP and the manufacturer involved, which was addressed with educational materials for GPs being distributed and communication in *Australian Family Physician*.

There are further analyses that could be undertaken using the TAPS data to improve our understanding of the errors reported, such as further statistical analyses using techniques such as building a model with multiple regression to determine significant factors that contribute to different error types. This work was beyond the scope of the TAPS study aims, but is part of further research recommendations.

In addition, future studies should address aspects of patient safety and reported error that it would not be possible to capture from the perspective of the reporting GP. Rather than one taxonomy which describes the reported errors from the GP's perspective in the way that the TAPS taxonomy does, it may be useful to develop a series of interlinked taxonomies that are directed to the needs of differing constituencies, such as the organisation providing health funds or the health insurer, the health regulators and legislators, and the patients or their significant others.

The assessment of potential and actual harms sustained by patients involved in reported errors is a further area of patient safety research that is difficult to comprehensively assess, and existing reporting systems in the literature, whilst addressing this from the reporter's perspective, require further work to improve the accuracy by which harm is measured and correlated with other data sets such as those managed by health insurers, and the experiences of people who are the subject of the reports.

The TAPS study presents a number of new findings about the nature of error and threats to patient safety that arise in the Australian health care environment, reported by a representative sample of general practitioners, and it is hoped that these will be

useful to all stakeholders in the health care setting, from clinicians, through to policy makers, and most importantly the patients who are the subject of the potentially preventable harms and near misses that are highlighted in this thesis.

1 Introduction

1.1 Purpose of the Threats to Australian Patient Safety

(TAPS) study - Why study patient safety events in the community setting?

The study of patient safety in community settings is recognized as a relatively under-researched area (Hammons, Piland et al. 2003). A stronger emphasis on community based patient safety research is important because the overwhelming majority of healthcare is delivered outside hospitals, in community settings (Green, Fryer et al. 2001).

Community based settings may hold distinctly different threats to patient safety from hospital settings due to the nature of the environment in which health care is delivered. Health professionals may have less continuity over patient care in some community based settings than in a hospital admission in which the patient is constantly under supervision, and more than one site is often required for an episode of care (having implications for patient and information transfer). Sites are not necessarily designed for providing healthcare (for example: patients' homes, providers' cars, on roads, or anywhere else, in fact).

Additionally, it may not be the rare mistakes with the drastic consequences that place the most burden on health systems, but possibly the more mundane threats to patient safety that may be less disabling when they cause harm, but have effects that are

magnified in community settings by frequent repetitions and exposure of a large number of people (Runciman, Edmonds et al. 2002).

1.2 Knowledge gaps in patient safety event research in community settings at the commencement of the TAPS study

The TAPS study protocol was written and funding applied for in early 2002, with NHMRC project grant funding for a three year period commencing in February 2003. At this time, a number of key patient safety organisations had not yet been established, such as the WHO World Alliance for Patient Safety (commencing in October 2004), and the Australian Commission for Safety and Quality in Health Care (commencing in January 2006). There was little activity worldwide on monitoring threats to patient safety in the community, as demonstrated later in the literature review of this thesis. There had been no studies in the community setting using the incident monitoring technique to obtain error or safety information from a randomly selected and representative group of primary care clinicians. The estimation of reported error rates in the community setting had not been attempted with any rigour. There had been no taxonomy established in primary care either in Australia or internationally as a preferred method of classifying reported errors.

The TAPS study remains as the only collection of data of reported errors in a community setting that has been based upon a randomly sampled representative cohort of general practitioners, submitting reports over a twelve month period with an anonymous secure online reporting system and allowing the collection of all patient

attendance data held by the Commonwealth Department of Health and Aging over the same time period. This allows a number of questions relating to the nature of threats to patient safety in the community setting to be addressed.

1.3 Major aims of the TAPS study

The TAPS study had the following major aims at its onset:

1. To design a web-based, secure and anonymous error reporting system that was suitable (in terms of access and ease of use) for Australian general practitioners.
2. To determine the incidence of reported error amongst general practitioners if a secure anonymous electronic reporting system is provided.
3. To quantify the types of errors reported by general practitioners if a secure anonymous electronic reporting system is provided.

As work towards the third aim progressed, it became clear that existing taxonomies did not meet the needs of clearly classifying the group of error reports, and so a subsequent aim of the project developed as follows:

4. To design a taxonomy for describing reported errors from general practitioners in the community setting that was comprehensive and reproducible amongst a group of clinicians, and that would be possible to adapt as a tool for clinicians to self-code reported errors.

1.4 Potential application of TAPS study findings

It was envisaged that the findings of the TAPS study would be of benefit to a number of groups, including:

- General practitioner participants who were embarking upon a process of professional development through reflection and self-directed learning.
- Health policy makers who would become better informed about the nature and extent of different types of reported threats to patient safety, and how best to direct resources to combat such threats.
- Patients, who it is hoped could benefit from practice changes made by their clinicians who participated in the TAPS study process and may have addressed particular errors in their practices after reflection and self-analysis, and any future resulting changes in policy or the health system.

There are several areas that could be explored in the Australian health policy context to support an error reporting system accessible to primary care clinicians modelled on the TAPS system. In addition to the points below, this is further discussed in this thesis in section 5.8 ‘Future directions – error analysis and feedback as learning tools for GPs and the primary care sector’.

1.4.1 Legislative changes

Protections for reporters could be considered in the form of legislative changes at state and federal levels that exempt the reports made to safety reporting systems from subpoena in an Australian state or federal courts. At a state level the application of qualified privilege legislation could also be explored to support the reporting process.

These protections could be introduced without impacting on other systems by which medical practice is regulated.

1.4.2 Incentives to encourage reporting

Incentives to encourage reporting could be considered in various ways. These could include funding accredited general practices which engage in error reporting and an associated reflection and learning cycle with some form of practice incentive payments. Other cost-offsets could be offered in the way TAPS participants were supported with small annual payments to cover internet or computing costs.

1.4.3 Error reporting as a continuing education activity

Positioning error reporting activities within a form of continuing education for general practitioners would also encourage reporting, and participation in reporting and learning audit activities could be rewarded with Quality Assurance and Continuing Education points towards the compulsory requirements for vocational registration in the way that the TAPS program was accredited by the Royal Australian College of General Practitioners as an audit activity.

1.4.4 Positioning an error reporting system in the practice

An error reporting system could be more accessible and quickly used if the system was built into existing medical records packages which could then send online reports. However it would be important to consider ways in which the data could be sent in either an anonymous fashion or with legal protections for reporters. There are issues of medicolegal risk for the reporting GP at present if there is a record kept in a patient file or a link between a report and a patient, and these would need to be overcome before such a package was acceptable.

1.4.5 Linking error warnings to general practitioner activity in real time

Medical software packages used for prescribing and recording other treatments could contain links to error warnings, generated from regionally or nationally reported data. For example, as a general practitioner selects a particular medication or treatment option, a pop-up link or brief information box could inform them if particular error types had been reported in association with this therapy, to highlight that risk as they were proceeding with the prescription or treatment.

1.4.6 Introducing error reporting guidelines in association with new practice accreditation standards

Australian general practice accreditation standards have been very recently changed by the RACGP to include that a practice has a system for monitoring and addressing events that could affect patient care, and so GPs would be receptive to being able to access a standardised system such as a national error reporting site to help address this new need. At present the standard has been introduced to the accreditation regime for practices with very little support or information on how a practice should best conduct this activity. At this point in time, we may therefore be at the beginning of a major rise in general practices acknowledging and addressing the fact that errors are part of patient care, and combining the knowledge and lessons learnt from individual GPs or small groups could provide major advances in patient safety in the community setting. An immense simplification of the process of analysing errors in general practices on regional, state and national scales would result if all practices were at least given guidance on what sort of system to use, even in advance of a centralised reporting system being available.

1.4.7 Modelling the safety culture and error reporting

Cultural improvements in clinician's attitudes towards patient safety will happen more readily if senior role models display the desired behaviours and the methods of monitoring and learning from patient safety events are begun in the early stages of a clinician's career. Medical curricula at undergraduate and postgraduate training levels could be enhanced and standardised in this area, to highlight the concepts of patient safety and reinforce the importance of learning from error. For example, a national reporting and learning site modelled on TAPS could provide audit style research activities for GP registrars and a focus for selecting topics for self-directed learning and study.

1.4.8 Providing positive feedback to users

General practitioners will value systems that improve their ability to provide good patient care, and this means that the focus of the introduction of any major error reporting system should be firstly on the benefits to the patient, rather than knowledge or financial incentives of any kind. The system should have a form of positive feedback to the user to remind and encourage them, noting that whilst they are always entering reports of possible poor outcomes or patient harms, their contributions are adding to essential knowledge that will hopefully contribute to system wide improvements and lead to tangible benefits for the community. A positive feedback newsletter or electronic transmission with recent findings and practice tips should be built in to the system.

1.4.9 Universally accessible website

Knowledge about errors occurring in health care settings could benefit patients as well as clinicians, who may be able to become better informed about the system in which

primary care is provided, its strengths and weaknesses. Access to a public area of a national safety reporting site where de-identified data and error stories are able to be presented and explained to the community could help with both raising the public awareness of areas of care that are perhaps higher risk, or even by simply improving public awareness that system and human errors are part of health care, and patients, clinicians and organisations need to acknowledge their existence in a collaborative way to foster improvements and changes.

2 Literature Review

2.1 Overview of the literature review

2.1.1 Literature review objectives and structure

The purpose of this section of the thesis is to review current understanding of reporting error and its measurement in the general practice and broader community setting, particularly considering the methods and measures that have been used in researching patient safety in community based care settings.

The structure of the review first addresses the methods applied to examine the literature, and then considers the findings in terms of the main themes that emerged, as detailed in section 2.1.4. These themes are expanded upon in sections 2.2 to 2.6. Section 2.2 discusses the context of error reporting in community settings, 2.3 discusses definitions and common understandings of concepts in error reporting, section 2.4 describes methods used to collect information on error, 2.5 discusses the types of errors reported in community settings and taxonomies of error, and 2.6 discusses aspects of the quantification of error in community settings.

Following this section 2.7 presents the main groups of studies contained in the review in table form describing their major features, section 2.8 expands upon the Australian literature, and the limitations of the review are discussed in section 2.9. Section 2.10 concludes with a summary of the main findings of the literature review.

2.1.2 A note on terminology used in the literature review

Throughout the literature review, there are many references to error reporting in the ‘community setting’. This term is used to be inclusive of the general practice setting which was the focus of the TAPS study. The international scientific literature uses a variety of terms that may encompass a ‘general practice’ setting as understood in Australia and the United Kingdom, or for a medically trained health professional who would be identified as a ‘general practitioner’ in Australia. These include ‘family practice’ and ‘family physician’, and in some cases the ‘primary care’ setting, and a ‘primary care clinician’, although the latter would have a different implication in Australia where general practice is a subset of primary care.

All of these terms may appear in the review, as an attempt has been made to reflect the origins of the works described, however the wording of ‘community setting’ should be understood as being inclusive of all of these terms, as all of these findings may be relevant to the Australian general practice setting.

Further, the terms ‘classification’ and ‘taxonomy’ are often used interchangeably in the scientific literature. ‘Taxonomy’ is the accepted term for a system to define, harmonize and group patient safety concepts, as used by the majority of publications that describe the classification of errors in community settings, in addition to the WHO World Alliance for Patient Safety on their website at <http://www.who.int/patientsafety/taxonomy/en/> (accessed 12th June 2007), who are currently leading a project to develop an internationally accepted taxonomy of patient safety. ‘Taxonomy’ is therefore used throughout the review to describe a system of classifying errors in the community setting.

2.1.3 Literature review methods

A comprehensive review of the published scientific literature was undertaken, using OVID Medline. Commencing in 1966, this collection includes In-Process & Other Non-Indexed Citations, Ovid's collection of non-indexed NLM records, both the in-process and PubMed-not-MEDLINE records, and OLDMEDLINE (the National Library of Medicine's online database of approximately 1,700,000 citations to articles from international biomedical journals covering the fields of medicine, preclinical sciences and allied health sciences). Details of the search strategy and results are shown below in Table 2.1.

Table 2.1 Search strategy used for OVID Medline

#	Search History	Results
1	exp Family Practice/	48951
2	primary care.mp. or exp Primary Health Care/	66109
3	General Practice.mp. or exp Family Practice/	59255
4	1 or 2 or 3	116178
5	exp Medical errors/ or error.mp. or exp Diagnostic Errors/ or exp Medication Errors/	130279
6	exp Risk Management/ or exp Medical Errors/ or incident.mp.	156757
7	exp Adverse Drug Reaction Reporting Systems/ or exp Medical Errors/ or adverse event.mp.	60157
8	exp Safety Management/ or exp Quality Assurance, Health Care/ or exp Medical Errors/ or exp Risk Management/ or patient safety event.mp. or exp Safety/	311300
9	5 or 6 or 7 or 8	408046
10	exp Insurance Claim Reporting/ or reporting.mp. or exp Adverse Drug Reaction Reporting Systems/ or exp Mandatory Reporting/	46498
11	4 and 9 and 10	346

A variety of Medical Subject Headings (MeSH terms) relating to patient safety, primary care and incident reporting were used to search Web of Science (general and related references), and Excerpta Medica (EMBASE), and the reference lists of selected articles were scanned for any additional relevant publications.

In addition to database searches, the internet sites of national patient safety organizations in Australia, Europe and North America and the English-language websites of 92 international, national or provincial general practice/family medicine organizations, one international and one national physician insurance agency have also been reviewed.

A complete set of articles identified in the search described above that related to patient safety in community settings and classified by topic, plus university departments, national and international organisations working in patient safety in community settings, is provided as Appendix 1.

2.1.4 Thematic structure of the content of the review

The findings of this literature review are presented within several major theme groupings, each of which is part of the overall picture of a current understanding of the elements that are known about the reporting of error and its measurement in the general practice and broader community setting. The themes may be grouped into two overarching areas, being the context in which error reporting occurs, and the nature of reported errors.

Figure 2.1 gives a pictorial representation of the context in which error reporting occurs, showing three major themes. Community expectations around error reporting, as set by legal boundaries in state and federal laws, provide the general background upon which error reporting occurs. Within this, the regulations and structures provided by professional bodies and health insurers further define the activities involved in reporting error. Third, central to the activity itself, are the attitudes and opinions of health professionals that engage in error reporting in the community setting.

Superimposed on this interpretation of the context in which error reporting occurs is a triangular pyramid which represents the nature of the activity of error reporting itself, and this is expanded in figure 2.2. This is designed to illustrate the major themes described in the literature on the nature of reported errors, and their dependence upon one another with the broadest concepts required to understand the nature of error at the bottom of the pyramid, and further themes building upon these.

The basis of the structure is the definitions and common understandings around error. Built upon this are the methods employed to gather information on patient safety events, followed by the types or taxonomic classifications of errors described by these methods, and the quantification of these error types reported in the community setting.

Figure 2.1 The context within which error reporting in the community occurs, represented by the elements of community expectations, professional organisations and attitudes and opinions of health professionals.

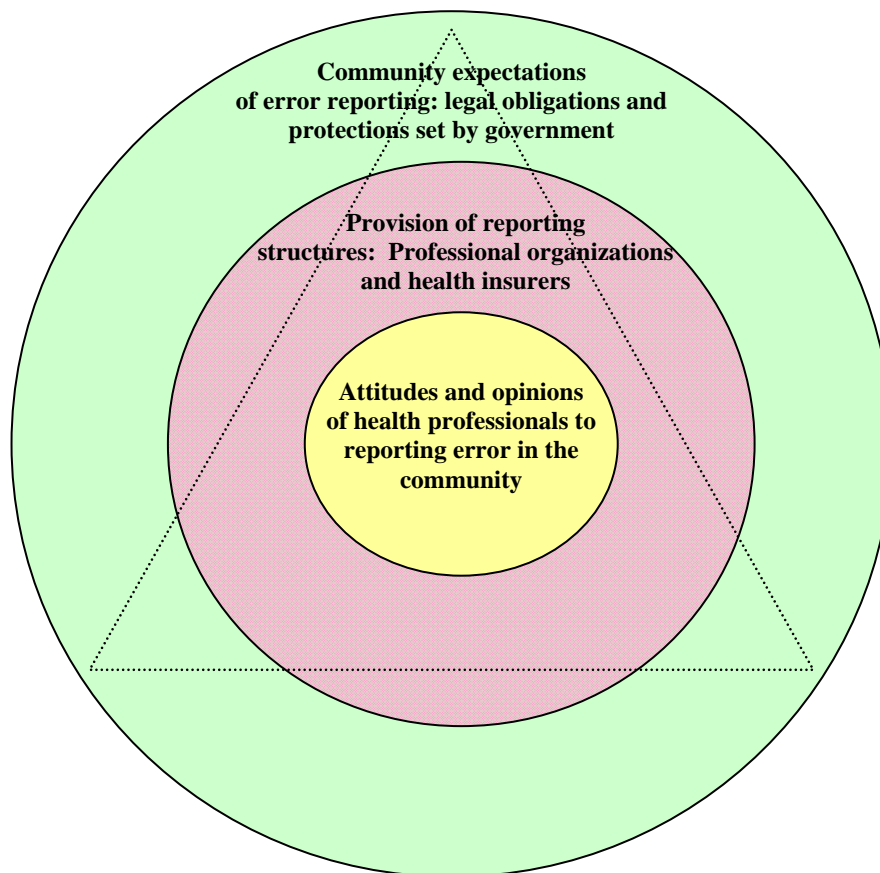
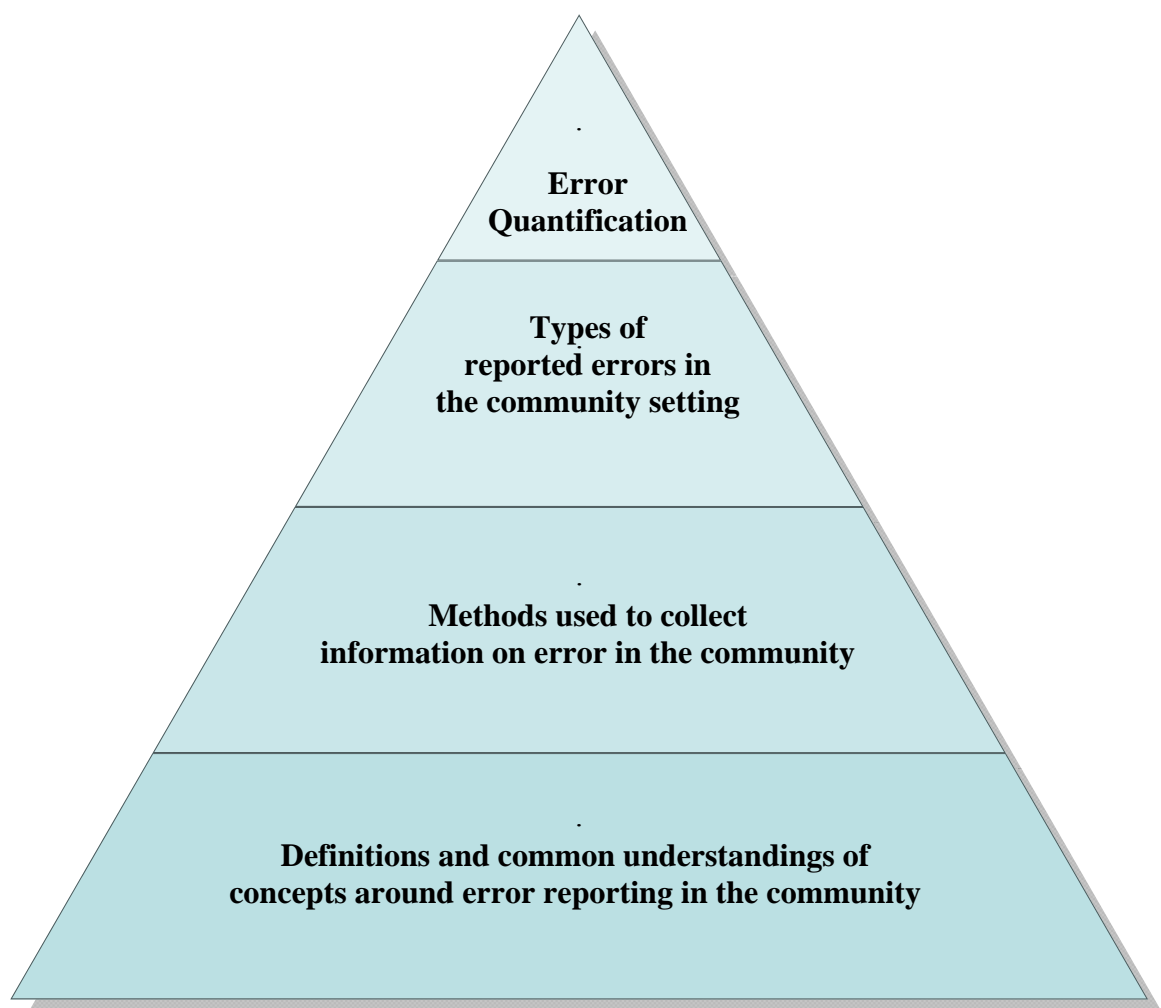


Figure 2.2 The major themes described in the scientific literature on the nature of reported error in community settings, including definitions, monitoring methods, types of errors reported, and their quantification.



2.2 The context of error reporting in community settings

The context or environment in which error reporting is occurring in the community has been measured in some studies found in the scientific literature, and these studies generally relate to the central concept in figure 2.1, being the theme described as attitudes and opinions of health professionals reporting error. Comment on the ‘safety culture’ in primary care reflects these attitudes.

No papers were found that specifically studied aspects of the next level of the reporting environment in figure 2.1, being systems provided to report or monitor error by professional organisations or health insurers. Appendix 1 however provides a list of professional bodies found to be engaged in this type of work, and some studies have looked at desired locations of error reporting systems, which provide some further comment on this theme and are discussed in more detail in this section of the review .

The third theme in this area is that of the general community expectations and this includes the varying legal protections that different countries afford health professionals reporting error. Some comment is made on the legal protections offered to reporters in a small group of papers, which are discussed in more detail below. Also discussed in relation to the broader community context is the balance between the interests of the individual clinician and the patient who may have suffered from being exposed to an error.

2.2.1 Attitudes of individual health professionals to reporting error: The 'safety culture' and barriers to enhancing safety in community settings

The safety culture in primary care has been recognized by many researchers as a key factor in improving the acceptance and development of enhancing patient safety in primary care. Patient safety may be improved through the cultural change associated with an increased awareness of the subject when systems are put in place (Dambro and Weiss 1988) (Coyle, Mercer et al. 2005).

It has also been shown that primary care clinicians suffer an emotional impact when mistakes are made, and there is a need to share experiences that diminish an ambient culture of perfectionism and recognize errors as a natural part of the health system (Newman 1996). The view is being actively promoted that human fallibility can be moderated, but it cannot be eliminated (Reason 1995).

There is a need for leaders in the system to encourage patient safety and in many countries an important way to do this is through event reporting. For this method to be successful, the system needs to be able to take action to prevent such problems from recurring (Wilson and Sheikh 2002; Wood and Nash 2005).

A recent qualitative focus group study of Family Practices conducted in the US examined barriers and motivators for making error reports, and concluded that successful error reporting systems for Family Physicians' offices need to have a low burden of effort to report, have great clarity regarding the information requested,

provide direct benefit through feedback useful to reporters, and take into account error severity and responsibility (Elder, Graham et al. 2007).

Numerous impediments to reducing threats to safety in community settings have been identified in the literature. These include a widespread misunderstanding about the nature of threats to patients in community settings, why they occur, the prevailing culture of "name and blame" surrounding these events, and fear of litigation if errors are acknowledged and reported (Kizer 2001). Other difficulties that need to be addressed to consistently measure patient safety in the community include the major variations that have been used to date in definitions, methodologies and the levels of legal protection offered in different settings (Jacobson, Elwyn et al. 2003; Sandars and Esmail 2003; Wood and Nash 2005).

Evidence from a recent survey of GPs' attitudes towards reporting and learning from adverse events supports the notion that primary care may be ready to overcome the above barriers. Conducted in Denmark with around 1200 participants, it concluded that GPs had a positive attitude towards discussing adverse events with peer groups as learning exercises, and towards reporting adverse events to a database if the system granted legal and administrative immunity to reporters (Mikkelsen, Sokolowski et al. 2006).

2.2.2 Professional organisations and providers of medicolegal insurance

The next level of the environment in which errors are reported is the professional organisations to which a potential reporter belongs and the providers of medical

indemnity insurance who request comment from their customers on events that could result in medicolegal risk. The latter also keep databases of claims which have occasionally been used to study patient safety events in community settings (Fischer, Fetters et al. 1997; Phillips, Bartholomew et al. 2004).

It is likely that a system located in a national organization focused on safety would be more readily accepted by potential users than one within a medical board or insurance organization (Beasley, Escoto et al. 2004). GPs in the Danish survey described earlier displayed a significant preference in reporting to a research institution over the latter options (Mikkelsen, Sokolowski et al. 2006).

There are a number of national and international professional organisations that engage in error reporting activities in the community setting, and these are listed in Appendix 1.

2.2.3 Broader community context in which error reporting occurs

The community in which individual health professionals and their professional organisations operate is ultimately responsible for monitoring and creating the legal boundaries that relate to reporting threats to patient safety. Apart from one paper which asked a very small non-representative community group for their view on errors that they had experienced (Kuzel, Woolf et al. 2004), there were no studies that examined this aspect of error reporting.

Some discussion was found in the literature of the legal context in which error reporting occurs. Many researchers have advocated a non-punitive approach to safety

event reporting (Wilson and Sheikh 2002; Beasley, Escoto et al. 2004; Wood and Nash 2005; Mikkelsen, Sokolowski et al. 2006). The recent Danish survey described earlier found 80% support for a model of confidential reporting where the recipient knows but conceals the identity of the reporter, versus only 35% supporting a ‘conditionally confidential’ model, whereby the names of reporters would be passed on in a case where the reporter may have breached a relevant law (Mikkelsen, Sokolowski et al. 2006).

There is also some debate in the literature over the benefit of a legally protected and confidential method versus an anonymous approach to reporting, with some advocating confidential reporting provides more detailed data and opportunities to further explore safety events (Pace, Staton et al. 2003). However the anonymous approach has been used in several studies and is more likely to prevent unwanted discovery of reporter details. To date, no reports of a legal challenge associated with a patient safety event reporting system in primary care have been found, so confidential systems are untested with respect to protecting reporters from legal action.

The WHO World Alliance for Patient Safety has produced draft guidelines for adverse event reporting and learning systems (Leape and Abookire 2005). This guide comments that reporting to most of these systems is voluntary, which invites a professional ethic of participation in continuous learning and prevention, encouraged by acknowledgement and the reward of visible change. It also notes that experience from outside of health care, particularly aviation, shows that reporting systems are more likely to be successful if those reporting do not need to worry about adverse consequences to themselves or others.

This attitude of health professionals to how the community should regulate their error reporting activities needs to be balanced with the interests of the individual patients who may have been injured as a result of an error. In Australian settings on balance, governments have supported the concept that error reporting should be non-punitive, with the earliest work on incident monitoring in general practice actually creating an Act of the NSW parliament to protect its participants from legal action as a result of participating in the study (Britt, Miller et al. 1997). Further, both the Commonwealth of Australia and the individual states of Australia provide a system of 'Qualified Privilege', which allows the records of specific activities which benefit the community but may pose a risk to participating health professionals to be protected from subpoena by decree from the relevant Minister. This is discussed further in the methods of this thesis, and was granted by the NSW Minister for Health in the TAPS study.

2.3 Definitions and common understandings of concepts in error monitoring

As shown as the broadest base for understanding the nature of reported error in figure 2.2, the definitions of error, harm and safety in the scientific literature are an important starting point when considering aspects of monitoring and measuring threats to patient safety in community settings.

There is no single definition that stands out as the accepted meaning of what should define a patient safety event in a community setting. The literature on patient safety in community settings has used a range of definitions of error, usually focused around the notion of whether or not the reporter of an event should base their inclusion of the incident on whether or not a patient may have been harmed, or potentially harmed. In some cases, no clear definition is reported. In most studies reviewed, the concepts of ‘harm’ and ‘safety’ were not clearly defined, despite their inclusion in the definition of ‘error’. Various leading researchers and organizations in the field have produced documents suggesting preferred definitions (Runciman 2006; WHO World Alliance for Patient Safety 2006), and shared concepts and standard definitions are a necessary concept for the field of patient safety to progress (2003). The definitions adopted in each group of studies are detailed in the descriptions of their methodology (in section 2.7, part A).

Further discussion of the rationale for the definition of error adopted for the TAPS study is discussed in Methods, Section 3.5 of this thesis.

2.3.1 Current definitions in the Australian context

The Australian Commission on Safety and Quality in Health Care was established in 2006, and in terms of defining error has followed the lead of a recognised expert in the field, James Reason. Although no Australian studies in community settings have applied these, it has recently published the definitions (shown in figure 2.2) on its website (WHO World Alliance for Patient Safety 2006), which appear quite broad and not restricting the interpretation of whether an error has occurred to the presence of patient harm:

Figure 2.3 Definitions of error, harm and safety described by the Australian Commission on Safety and Quality in Health Care, accessed Jan 7th 2007 at <http://www.safetyandquality.org/internet/safety/publishing.nsf/Content/former-pubs-archive-definitions#> .

Error	Error will be taken as a generic term to encompass all those occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome, and when these failures cannot be attributed to the intervention of some chance agency (Reason,1990).
Error (active)	An error in which the effects are felt almost immediately (Reason, 1990).
Error (latent)	An error whose adverse consequences may lie dormant within the system for a long time, only becoming evident when they combine with other factors to breach the system's defences (Rasmussen, Petersen and Goldstein, 1994)
Harm	Death, disease, injury, suffering, and/or disability experienced by a

	person.(ACSQHC)
Safety	The degree to which the potential risk and unintended results are avoided or minimised. (ACSQHC).

2.3.2 Definitions used in the broader scientific literature in studies of error in community settings

Although one of the difficulties in comparing works published on this subject is the differences of definitions used, there are some common elements of the definitions of error to be found in many of them.

The most commonly shared concept is that events being measured could have resulted in a patient harm, and several studies mention the word ‘harm’ in their definition of error (Britt, Miller et al. 1997; Bhasale, Miller et al. 1998; Dovey, Meyers et al. 2002; Makeham, Dovey et al. 2002; Beyer, Dovey et al. 2003; Dovey, Phillips et al. 2003a; Dovey, Phillips et al. 2003b; Dovey, Phillips et al. 2003c; Pace, Staton et al. 2003; Fernald, Pace et al. 2004; Westfall, Fernald et al. 2004; Woolf, Kuzel et al. 2004; Rosser, Dovey et al. 2005; Shaw, Drever et al. 2005; Tilyard, Dovey et al. 2005; Kostopoulou 2006; Williams and Osborn 2006).

In other studies where the definition didn’t actually use the term ‘harm’, a common practice was to include very similar phrases that could be interpreted as such. For example, a US study of patient reported errors (Kuzel, Woolf et al. 2004) defined error for the participating patients as all forms of improper, delayed or omitted care that unnecessarily injures patients by either worsening health outcomes or causing

physical or emotional distress. An Israeli work from 2003 (Wilf-Miron, Lewenhoff et al. 2003) defined an adverse event as being “an unexpected occurrence during medical care, involving physical or emotional injury, or the risk thereof”: the latter was termed a ‘near miss’.

There was also an approach adopted to defining error in some works that described a process disruption, but did not have any relationship to or mention of harm, such as two UK studies which used a definition of error as being an event that was not completed as intended and/or meant that work was disrupted in some way (Rubin, George et al. 2003; Steele, Rubin et al. 2006).

Another angle taken on the definition of an error was concentrating on the way an event made the reporter feel, rather than the process or potential or actual consequences of events for patients. An early US work (Ely, Levinson et al. 1995) used the definition for ‘error’ as an act or omission for which the physician felt responsible and that had serious consequences for the patient. It does not define ‘serious consequences’ however, which allows a large degree of personal interpretation for the reporting physician. Australian studies of general practice trainees (Diamond, Kamien et al. 1995; Sim, Kamien et al. 1996) defined ‘positive incidents’ as events that had made trainees feel good or competent; and ‘negative incidents’ as events that had made them feel incompetent or unhappy with their performance.

In studies which looked at medicolegal data, interestingly there was no use of the term ‘error in their definitions of what was being measured. Definitions reflected the

setting, containing words like ‘liability’, as in Adverse Events in Primary Care Identified from a Risk-Management Database (1997) (Fischer, Fetters et al. 1997), which measured ‘adverse events’ and defined them as incidents resulting in, or having the potential for, physical, emotional or financial liability to the patient. Another later US work of this type (Phillips, Bartholomew et al. 2004) measured ‘claims’, and defined them as both cases where demands were made for compensation but no legal papers were filed in court, as well as formal litigation events. ‘Negligent claims’ were deemed by peer reviewers as legally indefensible, ‘non-negligent claims’ were defensible, and the defensibility of ‘other claims’ was undetermined.

Finally, some papers were very poor in their definitions of exactly what was being measured, with no definition really provided. A 1998 UK study examining deaths in a group of general practices (Holden, O'Donnell et al. 1998) stated that the classification of a death as a preventable event was agreed upon by the participating GPs, although no definition or criteria are described in the paper. Another paper that describes a model for using a computer system to visualize patient safety in primary care does not present any definitions of error or harm (Singh, Singh et al. 2005).

2.3.3 Definitions used in studies examining patient safety events in hospital settings

An important distinction to be made between patient safety studies in community versus hospital settings was the unit of ‘event’ being measured. Generally it is not possible to make comparisons between major works in the literature that have examined events in hospital settings such as the Harvard Medical Practice Study of

the mid 1980s (Brennan and Leape 1991; Brennan, Leape et al. 1991; Leape, Brennan et al. 1991), or the Quality in Australian Healthcare study of the early 1990s (Wilson, Runciman et al. 1995), as their basic definition of what was being measured was an ‘adverse events’, which was something which resulted in actual patient harm, but did not necessarily involve a system or human error. This varies significantly from studies conducted on patient safety in community settings, which have almost all adopted an incident monitoring approach and an accompanying definition of error which considers disrupted processes rather than outcomes.

2.3.4 Definition of error used in the TAPS study

The TAPS study was commenced in 2003, prior to the Australian definitions being proposed by the Australian Commission for Safety and Quality in Health Care (ACSQHC) presented in section 2.3.1. The definition of error was taken from the pilot study, the Primary Care International Study of Medical Errors, (further discussed in section 2.8.4), where it was found to be very well understood by participants with almost no error reports received by the research team that did not comply with the definition (Makeham, Dovey et al. 2002).

The definition asked for participants to report any event that made them conclude *‘That was a threat to patient well-being and should not happen. I don’t want it to happen again’*. It differs mainly from the ACSQHC definition in that it does not matter what outcome resulted, rather it is concerned with anything that participants identified as something wrong, to be avoided in the future. The full definition and further discussion of its use are presented in the Methods section 3.5 of this thesis.

2.4 Methods used to collect information on error in the community setting

The next theme discussed here as an element of the nature of error reporting is an appraisal of the methods developed to collect error information in various studies.

2.4.1 Overview of error reporting methods

Methods used in studies in community settings that monitor patient safety events have predominantly used prospective event reporting, with survey designs ('incident reporting systems') (Britt, Miller et al. 1997; Bhasale 1998; Dovey, Meyers et al. 2002; Makeham, Dovey et al. 2002; Pace, Staton et al. 2003; Rubin, George et al. 2003; Wilf-Miron, Lewenhoff et al. 2003; Elder, Vonder Meulen et al. 2004; Fernald, Pace et al. 2004; Westfall, Fernald et al. 2004; Shaw, Drever et al. 2005; Makeham, Kidd et al. 2006; Williams and Osborn 2006). A small number of studies have used other methods including interviews with health care providers (Diamond, Kamien et al. 1995; Ely, Levinson et al. 1995), reviews of incident reports or malpractice claims data (Fischer, Fetters et al. 1997; Phillips, Bartholomew et al. 2004), and one study interviewing primary care patients (Kuzel, Woolf et al. 2004).

Although almost all of the methods employed in hospital-based research have also been used in research in community settings, there are some methodologies missing from the literature. No studies using direct observation of incidents or autopsy reports were found in the literature as have been described in hospital based studies, no long-term systematic initiatives to use mortality data in quality and safety improvement in general practice (Baker, Sullivan et al. 2007). Of particular note, no methods were

found that were directly comparable to the retrospective records reviews used in hospital-based patient safety studies and the measures that might arise from such reviews (with the exception of records review to investigate defined activities, such as prescribing).

National consistency in patient safety event reporting systems has been called for in several countries (Sheikh and Hurwitz 1999; Sheikh and Hurwitz 2000; Sheikh and Hurwitz 2001; Runciman 2002; Wood and Nash 2005; Makeham, Kidd et al. 2006), and the NHS in England and Wales established the first national on-line system (Shaw, Drever et al. 2005), and this is the only one known that is accessible to community based clinicians.

Much evidence of the design success of a system should be considered in terms of its ability to answer the research questions that it set out to answer, or provide the service or education to clinicians for which it was established. To date there is little critical appraisal of existing reporting systems along these lines, and further evidence is needed before one particular style of reporting model should clearly be supported over another.

A variety of models have been trialled using methods described previously, and in addition there are proposals for theoretical models of community based safety event reporting. An example is a 'systems engineering' approach created by a multidisciplinary team of a visual computer based systems, where the reporter would 'point and click' on a diagram to show where an error occurred in the system, and be

presented with further systems to enter more error information (Singh, Singh et al. 2005).

The WHO world Alliance for Patient Safety commissioned a report which defined the characteristics of a successful reporting and learning system, and these features are presented in figure 2.4 below, which provide a starting point for organisations wishing to establish such a system.

Figure 2.4 The characteristics of successful reporting and learning systems to enhance patient safety as defined by WHO World Alliance for Patient Safety.

- Reporting is safe for the individuals who report
- Reporting leads to a constructive response
- Expertise and adequate financial resources are available to allow for meaningful analysis of reports
- The reporting system must be capable of disseminating information on hazards and recommendations for changes

2.4.2 Incident reporting systems in community settings

Incident reporting systems were the most commonly used method to answer questions relating to types of safety events in community settings. There were variations in the style by which reports were collected, including completing a paper based pro-forma or questionnaire (Britt, Miller et al. 1997; Bhasale 1998; Rubin, George et al. 2003; Elder, Vonder Meulen et al. 2004), telephone reporting (Wilf-Miron, Lewenhoff et al.

2003), electronic transmission of reports (Makeham, Dovey et al. 2002), secure web-based reports (Shaw, Drever et al. 2005; Makeham, Kidd et al. 2006; Williams and Osborn 2006), or a combination of these (Dovey, Meyers et al. 2002; Pace, Staton et al. 2003; Fernald, Pace et al. 2004; Westfall, Fernald et al. 2004).

Reporter protections varied, with clinicians being anonymous (Makeham, Dovey et al. 2002; Makeham, Kidd et al. 2006), reporting confidentially (Britt, Miller et al. 1997; Bhasale 1998; Kostopoulou 2006), being identified (Rubin, George et al. 2003; Elder, Vonder Meulen et al. 2004), or a combination or option of these (Pace, Staton et al. 2003; Fernald, Pace et al. 2004; Westfall, Fernald et al. 2004). Some settings had varying legal protections in place to prevent litigation (Britt, Miller et al. 1997; Bhasale 1998; Wilf-Miron, Lewenhoff et al. 2003).

The profession of reporters also varied, so that some collections of data were general practitioners or family physicians only (Britt, Miller et al. 1997; Bhasale 1998; Dovey, Meyers et al. 2002; Makeham, Dovey et al. 2002; Elder, Vonder Meulen et al. 2004; Makeham, Kidd et al. 2006), while other studies used a variety of other community based medical, allied health, nursing, administrative and reception staff (Pace, Staton et al. 2003; Rubin, George et al. 2003; Wilf-Miron, Lewenhoff et al. 2003; Fernald, Pace et al. 2004; Westfall, Fernald et al. 2004).

In addition to varying types of participants in these studies and their reporting options and protections, a variety of definitions of what constituted a reportable event and classification systems used to describe events make the results of these studies difficult to combine or compare.

2.4.3 The individual dialogue approach to error reporting

There were two studies found in the literature that employed an entirely verbal communication approach to reporting error by clinicians in the community setting (Ely, Levinson et al. 1995; Wilf-Miron, Lewenhoff et al. 2003).

Firstly Ely's study used an in-depth interview design with qualitative analysis to determine the perceived causes of self-admitted errors from family physicians (Ely, Levinson et al. 1995). 'Error' was defined as an act or omission for which the physician felt responsible and that had serious consequences for the patient. 53 Family Physicians participated, including osteopathic and allopathic family physicians, in Iowa City, USA.

In in-depth 30 minute interviews, participants were asked to describe their most memorable errors and the perceived causes. Transcripts were audio taped and analysed to determine frequencies of different causes. Participants were also asked to rate 20 possible causes of error as contributors.

The findings describe 34 causes of error, fitting into four main categories: physician stressors, process of care factors, patient related factors, and physician characteristics. Patient adverse outcomes and malpractice claims were also recorded. A mean of 8 causes per error was reported, and 47% of reported cases resulted in patient death. In 26% of cases there was no adverse outcome. Malpractice suits arose from 4 of 53 errors. Of 70 physicians invited to participate, 10% could not recall any error. The

most common causes of error identified were hurry, distraction, lack of knowledge, premature closure of diagnostic process, and inadequately aggressive patient management.

The main problem with this method was that reporting was dependent upon events being 'memorable', and recalled details of events could have differed after varying time lapses. Also to note is that analysis was conducted on only one case of error per participant.

A more recent study by Wilf-Mirron undertaken in Israel used a risk-management process to apply aviation safety principles to incident reporting in a large ambulatory healthcare setting, and describe its implementation (Wilf-Miron, Lewenhoff et al. 2003). An adverse event was defined as "an unexpected occurrence during medical care, involving physical or emotional injury, or the risk thereof": the latter was termed a 'near miss'.

Maccabi Healthcare Services is an impressively large non-profit HMO in Israel, providing primary and secondary ambulatory services for 1.6 million members. Community based services were provided by 3000 physicians, GPs and specialists, and 2000 auxiliary medical staff. All administrative data and a portion of the medical data (diagnoses, prescriptions, laboratory tests and referrals) were linked online to a central system. Each site, including doctors' offices, served as a computerized work station.

A central risk management (RM) unit for the area was established in 1996. Strategies in risk management involved a multidisciplinary team and aviation personnel and psychologists from the Israeli Air Force. Adverse events were reported by medical staff via a telephone hotline to a member of the RM unit, who used a computerized system that structured event debriefing. This addressed what happened, how it happened and why it happened. The key principle was that events should serve for learning, not blaming, and official immunity from disciplinary acts was granted to voluntary reporters. The RM staff provided emotional support and medical guidance to the reporters, and the developed risk reduction strategies were distributed to all staff.

To analyse the results the aviation safety approach to data collection and analysis known as '5M' was adopted: Man (human factors); Machine (technological aspects); Medium (environmental factors); Mission (care-specific activities containing potential risks and hazards); and Management (managerial regulations and staff aspects). A root cause analysis of over 2000 encounters in a 5 year period was presented. Errors were related to: processes of care, such as failure to order a test or make a referral (33%); treatment, such as medication errors (21%); judgment, such as under estimation of symptom severity (18%); auxiliary tests, such as imaging (15%); and poor physician-patient communication (13%).

The system was highly supportive of medical staff, and provided medico-legal protection, support and guidance when they were faced with an error. These factors are likely to be of great importance to primary care medical staff, who often work in a more isolated environment than hospital based doctors. Based on aviation industry

experience, the authors suggest that direct reporting captures better detail through in-depth dialogue than written reports.

Although the method described in this Israeli study has many impressive features, the individual dialogue approach to reporting has cost, medico-legal and practicality issues that make it difficult to replicate in many other community settings. This quite impressive system would likely come at a significant financial cost to establish and maintain.

2.4.4 An example of a national error reporting system available in the community setting

Two papers were found in the scientific literature that describe a national system for adverse event and near miss reporting in England and Wales (Shaw, Drever et al. 2005; Williams and Osborn 2006). To date, this system established by the National Patient Safety Agency of the NHS in England and Wales represents the only known adverse event reporting system that has been provided at a national level using a secure anonymous online method, which is accessible to clinicians in a community setting as well as a hospital setting.

In this system, an incident was defined as any event causing harm to a patient (adverse event) or an event that might have resulted in harm (“near miss”). The publications available to date describe its establishment, initially in 18 NHS trusts in England and Wales, including one that was a Primary Care Trust (most were acute care).

In the paper by Shaw, the National Patient Safety Agency (NPSA) received data from participant trusts electronically. Patient and institution names were removed prior to data transfer to the NPSA. Due to major inconsistencies in the systems each used, analysis was undertaken manually by the NPSA determining: time, date, patient age, sex, clinical specialty, location, risk rating, outcome for patient, type of incident and description of incident.

The other publication by Williams and Osborn describes developments in reporting techniques, and in September 2004 the NPSA opened an anonymous on-line web-based reporting route for staff who did not want to report via their host organizations. This system can be viewed at:

<http://www.npsa.nhs.uk/health/reporting/reportanincident> (accessed 3rd Nov 2006).

Some results were presented in the publications. Outcome gradings of incidents were recorded using 5 descriptors: catastrophic, major, moderate, minor and none. Type of incident was described by a two level categorization with 12 main categories: Slips, trips and falls; Medication management; Resources; Treatment; Medical records; Violence, harassment and aggression; Medical devices; Abscondment; Patient management and progress monitoring; Self-harm and suicide; No classification available. There were 33 end classifications within these 12 groups.

Shaw describes 28 998 incidents collected in a nine month period (95% were from acute care trusts). Over 20% of the incidents described as having catastrophic or major outcomes occurred in the patient's home or a residential care unit. 'Slips, trips and falls' was the most commonly reported incident type. Only 32 reports came from

the participating primary care trust. Williams and Osborn go on to state that a further 303447 reports were received between 2003 and 2005, and provides a series of 'lessons' for other countries to use when embarking on setting up a system such as this.

The system described is an attempt to integrate data on patient safety from many different health care settings with a large variation in the services delivered. The difficulties described in the papers demonstrate well the importance of planning a unified reporting and analysis system if different health settings are to attempt to combine their activities.

The findings presented to date on event type and outcome presented by Shaw *et al* are not able to be generalised because only 18 of the 700 trusts in the region were included in the study. Although these were all selected because they were thought to have adequate managerial support to engage in risk management activities and an IT based reporting system, there were many difficulties with integrating their data. There is no information on the size of the participating primary care trust or its reporting profile. The very low number of reports from that trust may indicate that the system was not feasible in a primary care setting.

Little more is gained in terms of information for the community setting in the second publication from Williams and Osborn, as there is very little quantitative analysis of the 303 447 reports collected between 2003 and 2005, and no descriptions relating to data received from primary care trusts. However, the website referenced in this paper provides an excellent patient safety resource for health workers in the NHS, and the

web based anonymous reporting tool provides a model for other countries wishing to take this approach.

2.5 Types of errors reported in the community setting

The next theme in this review related to the overall types of errors that are described in community settings in the scientific literature. Some studies have developed taxonomies of error, while others have not attempted to do this but still provide some rich information on the types of errors that occur. Overall there is relatively little information available on the proportions of types of patient safety events that are reported in general practice and other community settings, and no taxonomy that is widely used by general practitioners (GPs) to describe these events.

Previous studies in primary care have provided descriptions of the relative proportions of different types of patient safety events that they have collected, (Ely, Levinson et al. 1995; Britt, Miller et al. 1997; Fischer, Fetters et al. 1997; Bhasale, Miller et al. 1998; Dovey, Phillips et al. 2003c; Rubin, George et al. 2003; Wilf-Miron, Lewenhoff et al. 2003; Elder, Vonder Meulen et al. 2004; Phillips, Bartholomew et al. 2004; Rosser, Dovey et al. 2005) but none have been based upon a representative sample of primary care clinicians contributing data, and all have used different classification methods.

Only seven groups of studies that propose a taxonomy for describing safety events in the community setting were identified in the literature (Dovey, Meyers et al. 2002; Makeham, Dovey et al. 2002; Rubin, George et al. 2003; Elder, Vonder Meulen et al. 2004; Fernald, Pace et al. 2004; Kuzel, Woolf et al. 2004; Kostopoulou 2006; Kostopoulou and Delaney 2007). These classifications fell into two main categories:

(1) ‘multi-axial’ taxonomies and (2) ‘domain specific’ taxonomies, or more simple classifications describing a single element of the safety event. The former incorporate a number of different aspects about a safety event into its coding, such as the nature of the event, associated harm, patient and reporter factors, or cognitive factors in its causation.

There have also been some recent calls for classifications that address cognitive psychological processes (Zhang, Patel et al. 2004), and one has been developed for general practice (Kostopoulou 2006), also yet to be tested. Finally, one taxonomy has been described that is based upon patient’s perceptions of harms in primary care, although it has a limited application in terms of categorizing causes of events (Kuzel, Woolf et al. 2004).

The domain specific taxonomies identified focus mainly on the nature of the event in categories with a mixture of clinical and administrative titles. The various domains that have been measured in community based patient safety event taxonomies are detailed below in figure 2.5.

Figure 2.5 Features of a patient safety event described by taxonomies developed in community settings.

- Nature or descriptive type of event
- Location of event
- Mitigating factors associated with an event
- Outcomes of event, including patient harm
- Patient factors, such as age, gender and ethnicity
- Reporter factors, such as profession
- Preventative factors relating to an event

At present, the WHO World Alliance for Patient Safety is in the process of drawing together existing theories on this subject in both community and hospital settings, and has a Drafting Group who are presently undertaking a project to develop a proposed “International Patient Safety Event Classification”. Their second report was published on the WHO website in 2006 (WHO World Alliance for Patient Safety 2006), and describes their progress towards establishing guidelines and a consultative process for completing this task.

Not all of the taxonomies in the literature proposed for community settings have been tested, and in those that have, there are major limitations to consider with respect to their validity and comprehensibility. None of the studies attempted to test the reproducibility of their proposed taxonomies across different analysts or primary care clinicians. Of all the studies identified discussing safety events in community settings, only the TAPS study used a representative sample (Makeham, Kidd et al. 2006). Although a taxonomy developed to cross disciplines has been proposed (Chang, Schyve et al. 2005), it also remains untested with clinicians in the community setting.

2.5.1 Multi-axial taxonomies

‘Multiaxial taxonomies’ have been suggested as better tools to capture different elements of an event in addition to its description and causation, such as harm levels, location, participants or preventability. Examples include the taxonomy used by the Applied Strategies for Improving Patient Safety (ASIPS) collaborative in the United

States (USA) (Fernald, Pace et al. 2004), and the cognitive psychology based taxonomy developed recently by a group in the UK (Kostopoulou 2006).

These taxonomies are appropriate tools if the research question requires a detailed measure of a safety event at multiple levels, as when the research attempts to address the complexity of the underlying causation and associated features of specific event types. This process is carried out by specifically trained coders and analysts, following notification of a patient safety event by a healthcare provider or patient. Other multi-axial taxonomies that have may also be appropriate for community based settings but have not yet been field tested there. An example here is the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Patient Safety Event Taxonomy (Chang, Schyve et al. 2005).

2.5.1.1 Applied Strategies for Improving Patient Safety (ASIPS)

The best example of a large multiaxial taxonomy in use in the community setting is that developed by the ASIPS collaborative based in Colorado, USA (Pace, Staton et al. 2003; Fernald, Pace et al. 2004; Westfall, Fernald et al. 2004). This work was a multi-institutional, practice based project designed to collect and analyse data on medical errors occurring in primary care offices, and to develop interventions to reduce those errors. ASIPS included a voluntary Patient Safety Reporting System (PSRS) that captured anonymous and confidential reports of medical errors. The study aimed to develop the PSRS database (designed to capture error detail while protecting the identity of reporters and the details of the events themselves from discovery and thus potential use in medico-legal action against reporters), to develop a reporting system that physicians and staff would use, to describe the types of errors

reported by confidential and anonymous reports and highlight differences between them, and to develop interventions to decrease errors and improve quality of care.

Participants were asked to report “any event you don’t wish to have happen again that might represent a threat to patient safety”, including events associated with clinical judgment and knowledge, administrative procedures, and “near misses”, which were defined as events where threats to patient safety happened but no harm occurred. Over 475 physicians, nurses and other clinical and administrative staff from two practice based primary care research networks (urban and rural) in Colorado, USA.

The reporting method described was that a primary care provider who was aware of a patient safety event reported it using an automated telephone hotline, a website, or in paper form. Reports were either confidential (reporters provided their identity, answered one free-text question and were followed up by ASIPS staff on phone, following which reports were de-identified) or anonymous (reporters identified their role and practice type but not their identity, then answered a series of free text and multiple choice questions about the event and patients involved).

Errors were analysed by the research team using a measure adapted from an insurance company taxonomy, with the three members of the research team consensus coding the reported errors. The final measure contained 10 axes with 5 domains: patient characteristics; participants; course of events; outcome; and event discovery. There was hierarchical sub-categorisation within each section. Several codes could be chosen within a number of the domains for each report. Harm was assigned one of five categories for each report.

The results published to date concluded that over 800 reports had been received by February 2004. Anonymous reports provided less detail than confidential reports, with root causes less frequently identifiable. Database design features and administrative system features to overcome medico-legal detection threats were presented. An analysis of 608 reports was described, with two thirds of reporters using the confidential rather than anonymous system, and physicians chose the anonymous method more often than office staff. Common error types related to diagnostic tests (47%), medication (35.4%) and communication (70.8%). A clinical steering committee developed interventions to reduce error in commonly occurring areas, and alerts were issued to practices.

The ASIPS study has a number of strengths. Having alternative reporting options available may improve capture of events over methods concentrating on a single reporting tool. Demonstrable patient safety improvements in the form of alerts to practices resulted from this project. The full taxonomy is available online at www.cudfm.org/carenet/asips/taxonomy. It has links to the International Classification of Primary Care (ICPC) (Lamberts, Meads et al. 1985), which could be useful in considering error types associated with types of episodes of care. It contains detailed descriptions of some sub-levels, with up to 7 layers within several of the hierarchical categories.

The methods have a number of weaknesses however, and although this study addresses the medicolegal needs of one US state, it may not be so applicable in different legal environments. Stringent data security processes were followed but

even so, ASIPS had no control over the legal discovery of report data by subpoena, for their own or any linked organizations.

In terms of the taxonomy itself, there is no information presented on the reliability of the full ASIPS taxonomy and only the main axes and domains have been published in peer-reviewed literature. It is difficult to determine the link made by the authors between the descriptions of the nature of errors reported and the application of the taxonomy's '10 axes with 5 domains'. Looking at the link provided to the taxonomy website, the tool itself is enormous with literally hundreds of lines of code, which would be very difficult for a national system where GPs might be asked to self-classify the errors reported. There may be some overlap within these detailed descriptions and further work on the reproducibility and ease of classification using this tool would be helpful.

2.5.1.2 A multiaxial taxonomy of cognitive and system factors

Another example of a multiaxial taxonomy developed in the general practice setting in the UK is that described by Kostopoulou (Kostopoulou 2006). This study aimed to develop a taxonomy of patient safety in general practice based on a theoretical model of human cognition. Further analysis and results of the study were published earlier this year (Kostopoulou and Delaney 2007). It differs dramatically from other taxonomies in use in patient safety, in that it is based on concepts from cognitive psychology. It is multiaxial as there are three separate 'domains' that are classified for each event.

A patient safety ‘event’ included in this study had to fulfil three criteria: be harmful or potentially harmful to patients; result directly from the process of care (rather than patient’s condition); and be unintended. The underlying theory and definitions of some terms based in cognitive psychology used in this paper are based on the JCAHO theoretical taxonomy (Chang, Schyve et al. 2005).

Participants were from five general practices in the West Midlands, UK, all suburban or inner city (Kostopoulou and Delaney 2007), and errors were reported for varying lengths of time from these locations, between 6 and 16 months. Reporting was open to clinicians, administrative staff, and others attached to practices such as community nurses, health-care assistants and physiotherapists. This study used a survey design to solicit reports that were then further investigated by interview and qualitative analysis. A confidential reporting method was used, and reporters were followed up with interview from the investigators. Taxonomy development was a continuous process that occurred as events were analysed.

The resulting taxonomy uses a theoretical model entitled the “information processing model” of human cognition. Events were classified at three levels. At level one, the ‘cognition’ level, the error is classified according to (a) the cognitive domain involved (perception, memory, situation assessment, response execution) and (b) the error mechanism, which is the ‘psychological’ mechanism through which the error occurred. At level two, immediate causes are identified, internal (affective, motivational, psychological or cognitive states) and external to the individual. At level three, the likely contributions to the event (‘performance shaping factors’), which are more remote causal factors are identified as either ‘work organization’ or

‘technical’, each with subcategories. The full taxonomy can be viewed at <http://qshc.bmj.com/supplemental> in association with the 2007 publication (Kostopoulou and Delaney 2007).

Data collection in this study resulted in a relatively small collection of 94 reports, and only 78 of these were related to patient safety and analysable. Further, only 47 of this group contained the ‘cognitive information’ required in taxonomic levels 1 and 2 to actually use the taxonomy that was developed. Therefore in order to describe the events and attempt to make a comparison to other work, the authors actually also present the findings in terms of a ‘clinical categorisation’, which is a basic list of 11 descriptive terms, and there is no explanation of the meaning of these categories, some of which seem to overlap. Using this clinical categorisation, the largest group of errors of the 78 classified were ‘administrative – mainly booking appointments and filing’ (25%). Using the cognitive taxonomy where possible, the level 1 classification found ‘situation assessment and response selection’ as the most often involved (45%). It was found at level 2 that ‘immediate internal causes’ proved difficult to identify in most cases because of insufficient information in the reports or subsequent recall when participants were further questioned by the investigators. More than one level 3 ‘performance shaping factor’ was found for each error reported in many cases, and they are described as ‘technical factors’ (contributing to 30 events) and ‘work organisation factors’ (contributing to 71 events), the latter being further categorised as ‘excessive task demands’, ‘fragmentation’ and ‘communication’.

The terminology in this cognitive multiaxial taxonomy is challenging, and not clearly explained, and although the concept underlying this taxonomy has some merit, in that

it should capture elements starting from an individual's cognition and move out to the environment that predisposes to error, the main difficulty with the taxonomy is that the language may be too complex for practical use, and probably requires a background in cognitive psychology to apply. It has moved well away from a descriptive approach of event type, and although it is based on a body of theory, the results of classification using the proposed tool may have limited use for policy makers who require a grouping of like events in terms of clinical categories. The data used to create the taxonomy came from only 47 events.

There is no information on the confidential method of collecting reports, proportions of different types of contributing participants, their reporting frequencies, who contributed to taxonomy development, or any description of the event types that were included using the proposed taxonomy. The patient safety measure requires more extensive testing of its validity, reliability and comprehensiveness.

2.5.2 Domain specific taxonomies

These most commonly describe 'event type' without necessarily incorporating a measurement of other aspects of the event such as location, provider, and associated harm. Due to their simplicity, they may be more practicable for broad application in community settings. They could appropriately address research questions about the types of patient safety risks occurring in community based settings, and their quantification.

There are several examples of domain specific taxonomies in the literature. These less complex taxonomies, such as that described in the literature relating to the

Preliminary Taxonomy of Medical Errors in Family Practice (Dovey, Meyers et al. 2002), the simplified three level taxonomy from the International Study of Medical Errors (Makeham, Dovey et al. 2002), or the taxonomy developed in a United Kingdom (UK) general practice study (Rubin, George et al. 2003), could be applied as tools that providers of community based care access in order to code event types themselves. An electronic event reporting system may also capture patient safety domains other than the causal and descriptive factors (such as a severity score, location, patient demographic factors, or reporter factors), which could be combined with a descriptive taxonomy to answer other questions about factors associated with specific event types.

2.5.2.1 A preliminary taxonomy of medical errors in family practice

Published in 2002 and 2003, this domain specific taxonomy is the earliest example of such a classification developed in the community setting (Dovey, Meyers et al. 2002; Dovey, Phillips et al. 2003a; Dovey, Phillips et al. 2003b; Dovey, Phillips et al. 2003c).

The study was initially commenced as a randomized controlled trial that aimed to compare paper and computer reporting of medical errors observed by family physicians. The rationale for this aim was that family physicians might feel better able to report more sensitive events using computer reporting, where stricter confidentiality protections are possible, although this primary objective was not met and the RCT results have never been published. A secondary goal of the study was to develop a preliminary taxonomy of primary care medical errors observed by family

physicians in their daily practice and this has been published (Dovey, Meyers et al. 2002).

Participants were told to “report anything that happened in your own practice that should not have happened, that was not anticipated and that makes you say ‘*that should not happen in my practice, and I don’t want it to happen again*’. It can be small or large, administrative or clinical – anything that you identify as something to be avoided in the future.” Reported events did not require the physician to identify an adverse outcome, or an actual or potential harm to a patient.

A group of 42 Family Physicians from different parts of the USA who belonged to the American Academy of Family Physician’s (AAFP) National Network volunteered to participate. Participants submitted 10 anonymous error reports using a questionnaire about the event over a four month period, five on paper and five via a purpose designed computer reporting form that was sent electronically to a central database.

A qualitative method was applied to review free text responses to the questionnaires and develop a draft taxonomy by one investigator. Following this two other investigators independently reviewed reports and assigned them a classification from this draft. The three investigators then revised the measure through consensus discussion.

There were 330 errors reported and a multi-level taxonomy was developed. The highest level divided events into ‘process’ or ‘knowledge and skills’ errors. Second level ‘process’ categories were: office administration, investigations, treatments, communication, and payment. Second level ‘knowledge and skills’ categories were:

execution of a clinical task, misdiagnosis, and wrong treatment decision. Some second level categories were further sub-classified (up to a total of four levels), and others had no further sub-classifications. Altogether there were 32 end-classifications. At level one, 86% of errors were 'process' and 14% were 'knowledge and skills'. It was found that family physicians reported a spectrum of error different from those identified in studies from hospital settings.

The study was deliberately developed to study 'mistakes' in medical care and it therefore did not focus on associated harm, which may have allowed a broader capture of safety events. The definition was developed by clinicians providing care in community settings and was accepted by them as comprehensible. The reported taxonomy was regarded by the investigators as a work in progress. It was developed from the data without direct reference to any pre-existing classification, and the investigators expected that the measure would become more sensitive with further use.

With respect to potential weaknesses in design, this study has been criticized for lacking a theoretical framework (Kostopoulou 2006) After level one, there was no guide or definition used when determining the type of category that constituted another tier within the hierarchical structure presented. Quantitative results could not be generalized due to the participant sampling being non-representative, and the error reporting method with a set number of errors being asked to be reported in the study period, rather than all errors noted. The taxonomy's absence of a 'not otherwise specified' group at the base of each branch of the structure could also pose difficulties in its application.

2.5.2.2 Error classification and method of detecting errors from a UK general practice setting

Developed in a UK general practice setting, another example of a domain specific taxonomy has been published. The paper describes this classification of errors and aims to assess the feasibility and acceptability of a method for GPs and administrative staff to report error (Rubin, George et al. 2003; Steele, Rubin et al. 2006). This taxonomy is quite simplistic in its design, and a subsequent pilot study adapted the method and used the error classification in optometric practices (Steele, Rubin et al. 2006).

An error was defined as an event that was not completed as intended and/or meant that work was disrupted in some way. Ten general practices in the North-East of England – 163 participants including 39 GPs, 20 nurses, 81 reception staff, 10 managers and 13 other staff (health visitors, midwives, community psychiatric nurses, and pharmacists) were involved in the initial study (Rubin, George et al. 2003). The subsequent study used ten community optometric practices in the UK (Steele, Rubin et al. 2006).

A pilot general practice reported errors in notebooks over a two week period. Based on this, two investigators developed an error classification and incorporated it into a reporting form. Participants in 10 practices recorded errors on these forms over a 2 week period, and reported on the number of available appointments in the period. Reports were anonymous. A questionnaire on acceptability was also completed.

A six category classification of errors resulted, with each category having between 0 and 6 sub-categories, resulting in 18 end classifications. The same six categories were used in the optometric practice study. 940 errors were reported in general practices, and the proportion of errors in the 6 categories were: 42% prescriptions (administrative, clerical, medication, inaccurate computer records); 30% communication (case notes missing, delivery of post, information missing, wrong case notes, message failure, referral errors); 16% equipment (computer, other); 7% appointments; 3% clinical (notes, diagnostic, therapeutic, omission); 2% others. The error rate was 75.6 per 1000 appointments. Participants found the method generally acceptable (<10% feeling threatened or finding the process disruptive).

The attractive thing about this taxonomy for broader application in the general practice setting was that the patient safety measure was derived directly from clinical practice and reporters themselves coded events. This may make it more practicable than a system requiring expert coders or risk managers to determine types of errors reported. Reporting was anonymous, which may also encourage reporting. However the classification and reporting method does not address underlying causation, harm levels, patient attributes and settings of events, and there may be problems with reproducibility. A high proportion of detected problems were administrative, possibly because most reporters were administrative staff. The paper-based reporting method raises issues of medico-legal risk as reports were hand-written. There was no discussion of linking reports to reporters or removing sensitive information on time, setting and location of events. The error rate and other findings cannot be generalized as the study sample was not representative of UK general practices or patients.

2.5.2.3 Patient reports of preventable problems and harms in primary care

Patient reports of preventable problems and harms in primary care was a study that provides a different type of domain specific taxonomy from any others presented in the literature, in that it is based on patients' perceptions of error and harm for general patient safety events (Kuzel, Woolf et al. 2004).

The study design used in-depth interviews of a random selection of patients to develop patient-focused measures of medical errors and harms in primary care and determine the most important to patients. Error was defined as all forms of improper, delayed or omitted care that unnecessarily injures patients by either worsening health outcomes or causing physical or emotional distress.

38 volunteers from Virginia and Ohio were recruited by random telephone calls from the local phonebooks. Participants were one-third male and two-thirds female. They were interviewed by trained investigators, using a standard guide. Interviews were taped and transcribed with personally identifiable information removed. Participants ranked their reported errors from least to most disturbing. A qualitative method of analysis was used to define event types.

A taxonomy of patient reported errors was organized around 5 domains: access breakdown, communication breakdown, relationship breakdown, technical error and inefficiency. Each domain was further categorised with up to 4 levels, and there were 70 end categories in total. Harm was assigned into 40 separate non-hierarchical categories.

Two hundred and twenty one ‘problematic incidents’ were described in 38 interviews. Breakdown in the clinician-patient relationship comprised 37% of these, and were dominated by stories of disrespect or insensitivity. One hundred and seventy reported accounts of harm were described and 70% of these were psychological harm.

This paper represents one of only two published studies in a community setting found relating to patients’ perceptions of error and harm for general patient safety events as opposed to specific topics such as medication events (Kuzel, Woolf et al. 2004; Phillips, Dovey et al. 2006). The paper reported on ‘problematic incidents’ but this term was not clearly defined. Cues to prompt interviewees were used - these may have influenced the results. Although a range of patient types were included amongst participants, the study involved a small non-representative sample of patients, and so there may be many error types that remain undetected. The study’s results demonstrated little association between patients’ impression of events and their treating physicians’: for example, that a misdiagnosis had occurred. The classifications of event types and harms would be difficult to apply to a clinician-reporting system. However the study highlights the importance of communication issues and the patient-doctor relationship in primary care as a source of harm to patients.

2.5.3 Evidence on types of patient safety events from studies examining medicolegal data in a community setting

There has been a small amount of work published that relates to types of errors found in the community setting based on analysing medicolegal claims databases. Two

studies that specifically undertook this task were found based in the US (Fischer, Fetters et al. 1997; Phillips, Bartholomew et al. 2004).

The first study in a community setting to use systematic risk-management record review methodology to measure the prevalence of adverse events in community care was published by Fischer in 1997 (Fischer, Fetters et al. 1997). This work analysed data reported in a risk-management database of an academic health centre to describe the prevalence of adverse events in the out-patient primary care setting. 'Adverse events' were incidents resulting in, or having the potential for, physical, emotional or financial liability to the patient. Incident reports from the database of an academic centre were collected over a 5 and a half year period (1991-96) from eight primary care clinics.

Two family physicians reviewed all reports to determine whether an incident was associated with medical management or due to some other cause, such as environmental.

If due to a medical error, one of four classes of causes was applied: diagnostic, treatment, preventive and 'other'. Adverse events were also classified as preventable or unpreventable.

The prevalence of incidents that resulted in an injury, potential injury, or financial liability was 5.4 per 100,000 clinic visits (51 cases), with 3.7 per 100,000 (35 cases) assessed as adverse events associated with medical management: 83% of the latter

were due to preventable error. The adverse events were due to treatment (31%), diagnostic mishaps (26%), 'other' errors (26%) or no error (17%), such as known complications. No adverse events due to preventive care were found.

The findings of this study may not be able to be generalised to other community settings as a single academic centre contributed study data. The method probably under-estimated the occurrence of adverse events and in more than half of the incidents, the reviewers could not agree on classification or preventability.

The second US study found in the literature of this nature was by Phillips (Phillips, Bartholomew et al. 2004), and used a large US malpractice database to describe the epidemiology of negligent adverse events from primary care (location, conditions, and attributable root causes of the claims). 'Claims' were defined as both cases where demands were made for compensation but no legal papers were filed in court, as well as formal litigation events. 'Negligent claims' were deemed by peer reviewers as legally indefensible, 'non-negligent claims' were defensible, and the defensibility of 'other claims' was undetermined. 'Underlying cause' was taken as the most significant medical misadventure identified by the insurer.

The study involved 49,345 primary care claims made between 1985 and 2000 to the Physician Insurers Association of America. Between 14 and 23 companies contributed to the database each year. Study data represented 361 member years (one company insured for one year) and over 1.8 million exposure years (one physician insured for one year). The analysis included claims made against family physicians and GPs, internal medicine physicians, and paediatricians.

Claims were analysed by study investigators to detect negligent adverse events. These were then analysed to determine the types of physicians involved, the severity of the outcome, the 10 most common associated medical conditions, the underlying cause, contributing factors and relative risk of negligent claims for specific medical conditions.

Severity of outcome was measured with 4 levels of harm (including death), underlying cause was described by 18 types of medical misadventure, contributing factors by 7 types presented from standardized insurance data, and background rates of medical conditions were determined from all 14 National Ambulatory Medical Care Surveys (NAMCS) conducted since 1980. Only five underlying causes appeared in 77% of claims: diagnostic error (34%), failure to supervise or monitor case (16%), improper performance (15%), medication errors (8%), failure/delay in referral (4%). Within contributing factors, problems with records were evenly distributed with respect to outcome severity, whereas high severity outcomes and death more often involved claims with communication between providers and early hospital discharge as contributing factors.

This data in this study was derived from a large number of physician exposure years, and rigorous measures were taken to compare the data on negligent claims per medical condition with background rates of medical conditions from a national US database spanning a similar time frame. For policy makers, this study is an excellent source of information to use in considering significant sources of morbidity and

mortality in primary care, and in determining medical conditions associated with a disproportionate number of negligent claims.

It is important to consider however, as the authors point out, that malpractice data represent a limited view of patients' experiences with patient safety events, missing many episodes that have no association with an insurance company. The underlying cause classification may have too few categories to use in patient safety research, and incidents may have been 'fitted in' to categories by reviewers regardless of their complexity. In addition, these categories may not reflect the range of event causes described other research on patient safety in this setting.

2.6 Quantification of errors in the community setting

The final theme to address with respect to the nature of reported errors in the community setting is the issue of their quantification. Although there are a number of studies which have described the types of errors we see in the community using the incident monitoring technique (Britt, Miller et al. 1997; Bhasale 1998; Bhasale, Miller et al. 1998; Steven, Malpass et al. 1999; Elder and Dovey 2002; Makeham, Dovey et al. 2002; Dovey, Phillips et al. 2003c; Rubin, George et al. 2003; Elder, Vonder Meulen et al. 2004), it is very difficult to quantify the number of errors occurring in the community setting in a given period of time. This estimation is important as it has major implications when directing resources that aim to combat such threats to patient safety.

Attempts have been made to estimate the incidence of errors in hospital settings, ranging from an adverse event rate of 3.7% of hospitalizations in the Harvard Medical Practice Study (Brennan, Leape et al. 1991), to 16.6% in the Quality in Australian Health Care Study (Wilson, Runciman et al. 1995).

In the community setting however, there is little, if any, data available concerning the incidence of error. A recent study of 15 Family Medicine Physicians in Cincinnati, USA, showed that the doctors identified errors in almost one quarter of their clinical encounters, although this was not able to be generalized (Elder, Vonder Meulen et al. 2004). An error rate of 75.6 per 1000 appointments over a two week period in 10 general practices in the North-East of England was based on reports from both clinical and administrative staff (Rubin, George et al. 2003). A review of a large US malpractice database over a five year period found that problems with records were

evenly distributed with respect to outcome severity, whereas high severity outcomes and death more often involved claims with communication between providers and early hospital discharge as contributing factors (Phillips, Bartholomew et al. 2004). However malpractice data represent a limited view of patient safety events, missing many episodes that have no association with an insurance company, and it has been suggested that there is no case for claims reviews which rely on data which have been assembled for legal purposes only (Vincent, Davy et al. 2006).

As there are so few studies that attempt to quantify reported error in the community, there was no specific discussion found in the literature regarding the barriers to undertaking such quantification. A likely reason could be that in order to answer research questions of this nature, careful attention to study design, especially in relation to representative participant sampling and numbers of patient encounters by participants in a given time period, need to be undertaken so that numbers of errors reported can be measured in some logical context that can then be generalised. Prior to the TAPS study, this was not done in studies of error in the community setting described in the literature.

Finally, it is important to note that the results of studies asking questions relating to the prevalence of safety events using incident reporting were likely to have been limited by the fact that reporters may not recognize safety events, or choose not to report for a variety of reasons.

2.7 Comparative tables of studies measuring patient safety events in community settings identified in the literature

In this section of the literature review, summarized in the following tables are 16 groups of studies identified within three main types relating to the measurement of patient safety events. These summary tables are designed to assist in an overview of the literature to date that deals with taxonomy of error and the general description of patient safety events in the community setting. They are presented in chronological order with aims, data collection and analysis methods, and major findings:

Type 1: Studies proposing a taxonomy of safety events in community settings (7)

Type 2: Studies describing types of safety events seen in community settings (6)

Type 3: Studies that measure other aspects of safety events in community settings (3)

Table 2.2 Type 1 - Studies proposing a taxonomy of safety events in community settings.

Study	Aim of research	Data collection method	Measurement method	Major findings
1. Dovey <i>et al</i> (2002-03) (Dovey, Meyers <i>et al.</i> 2002; Dovey, Phillips <i>et al.</i> 2003a; Dovey, Phillips <i>et al.</i> 2003b; Dovey, Phillips <i>et al.</i> 2003c)	Describe the types of errors reported in daily practice by family physicians and develop a taxonomy of error	Errors reported by 42 family physicians using both paper and computer based questionnaires	Four level taxonomy with 32 end codes, based on two main error types of 'process' or 'knowledge and skills' as underlying cause at level 1	A different spectrum of error types was reported by family physicians than has previously been described in hospital based studies
2. Makeham <i>et al</i> (Makeham, Dovey <i>et al.</i> 2002), Beyer <i>et al</i> (Beyer, Dovey <i>et al.</i> 2003) Woolf <i>et al</i> (Woolf, Kuzel <i>et al.</i> 2004) Rosser <i>et al</i> (Rosser, Dovey <i>et al.</i> 2005) Tilyard <i>et al</i> (Tilyard, Dovey <i>et al.</i> 2005) (2002-05)	To describe the types of errors reported by GPs and family physicians in 7 countries and develop an international taxonomy of error	Paper and computer based questionnaires submitted by 100 GPs and family physicians over a four month period	Multiple level taxonomy with 172 end codes, based on two main error types of 'process' or 'knowledge and skills' as underlying cause at level 1	Around 80% or reported errors were caused by 'process' problems, and 20% by deficiencies in 'knowledge and skills'.

Study	Aim of research	Data collection method	Measurement method	Major findings
3. Pace <i>et al</i> (Pace, Staton <i>et al.</i> 2003), Fernald <i>et al</i> (Fernald, Pace <i>et al.</i> 2004), Westfall <i>et al</i> (Westfall, Fernald <i>et al.</i> 2004) Parnes <i>et al</i> (Parnes, Fernald <i>et al.</i> 2007) (2003-07),	Develop a system for confidential error reporting, describe types of error and differences between confidential and anonymous reports	Confidential or anonymous reports submitted by phone, electronically, or on paper from 33 practices with 475 clinicians and staff	ASIPS taxonomy is a multiaxial system having 5 domains: patients, participants in event, outcome of event, course and cause of event, and event discovery. Harm was assigned to one of 5 groups.	Confidential reports afford greater analysis of cause than anonymous ones. Common errors types reported were diagnostic tests (47%), medication (35.4%) and communication (70.8%).
4. Elder <i>et al</i> (Elder, Dovey <i>et al.</i> 2002 and Elder, Vonder Meulen <i>et al.</i> 2004) (2002-04)	Describe errors identified by family physicians and determine physician's perception of resulting harm	Errors noted by family physicians on a proforma during half day sessions followed by interview with researchers	Classification by 'preventable adverse event type' (diagnosis, treatment or preventive service) and 'process error' (clinician, communication, administrative and 'blunt end' factors)	Errors reported in 24% of clinical encounters, and harm or potential harm reported in 24% and 70% of patients where error was noted respectively. Administrative errors were most common type reported.
5. Rubin <i>et al</i> (Rubin, George <i>et al.</i> 2003), Steele <i>et al</i> (Steele, Rubin <i>et al.</i> 2006) (2003-06)	Classify general practice errors and assess a reporting method for administrative staff and GPs	Events reported using an anonymous paper form, reporters coded events using a descriptive classification	Classification had 6 main categories: Prescriptions, Communication, Appointments, Equipment, Clinical Care and 'Other'	Practices found anonymously reporting errors using a simple paper form neither disruptive nor threatening. Most reported errors were administrative.
6. Kuzel <i>et al</i> (Kuzel, Woolf <i>et al.</i> 2004) (2004)	Develop patient-focused typologies of medical errors and harms in primary care	Structured interviews with 38 people recruited from phonebook.	5 domain taxonomy (4 levels, 70 end classifications): access breakdown, communication and relationship breakdowns, technical errors and inefficiency	Breakdowns in the clinician-patient relationship represented 37% of incidents, dominated by disrespect or insensitivity. 70% of reported harms were psychological.
7. Kostopoulou (Kostopoulou 2006), Kostopoulou and Delaney (Kostopoulou and Delaney 2007) (2006-2007)	Develop a taxonomy of patient safety in general practice based on cognitive psychological theory	Confidential reports received from 5 general practices in UK with follow up interviews from investigators	A three level taxonomy: level 1 'cognitive domain' that failed, level 2 are immediate internal and external causes, level three are 'performance shaping' factors	77 events contributed to taxonomy development. "Situation assessment and response selection" is the most frequently involved domain. Further testing of the model is required for validity and comprehensiveness.

Table 2.3 Type 2 - Studies describing types of safety events seen in community settings.

Study	Aim of research	Data collection method	Measurement method	Major findings
1. Diamond <i>et al</i> (Diamond, Kamien <i>et al.</i> 1995) and Sim <i>et al</i> (Sim, Kamien <i>et al.</i> 1996) (1995-96)	Describe GP trainee experiences with positive and negative incidents	Qualitative analysis of open-ended interviews with GP trainees	The 15 most frequent of 36 descriptive groups of critical incidents were reported	Analysis of critical incidents can accelerate learning and help plan curricula
2. Ely <i>et al</i> (Ely, Levinson <i>et al.</i> 1995) (1995)	Determine perceived causes of family physician error	Qualitative analysis of in-depth interviews with 53 Family Physicians	34 causes identified falling into 4 main groupings	Most common causes were hurry, distraction, lack of knowledge, premature closure of diagnostic process, and inadequately aggressive patient management
3. Fischer <i>et al</i> (Fischer, Fetters <i>et al.</i> 1997) (1997)	Describe the prevalence of adverse events identified through a risk-management database	Review of all incident reports from the database of an academic center over a 5.5 year period	Classification of causes into 4 types: diagnostic, treatment, preventive and 'other'	Adverse events associated with medical management were detected in 3.7 per 100,000 clinic visits. 83% were due to preventable error
4. Britt <i>et al</i> (Britt, Miller <i>et al.</i> 1997), Bhasale <i>et al</i> (Bhasale 1998; Bhasale, Miller <i>et al.</i> 1998) (1997-98)	Describe incidents occurring in general practice	Modified critical incident technique, with participants anonymously submitting paper reports	Participants selected from four incident categories, and four 'problem areas' identified by investigators	The incident monitoring technique can be successfully applied to general practice. 76 % of incidents were preventable, major harm occurred in 17%, and death in 4%
5. Wilf-Miron <i>et al</i> (Wilf-Miron, Lewenhoff <i>et al.</i> 2003) (2003)	Apply aviation safety principles to reporting errors in a large ambulatory healthcare setting	Events reported by telephone hotline to a specialized risk management unit for debrief and analysis	'5M' model from Aviation safety: Man (human factors), Machine (technology), Medium (environmental), Mission (care activities), Managerial aspects.	Root cause analysis of 2000 errors over 5 years: 33% processes of care; 21% treatment; 18% judgment; 15% auxiliary tests; and 13% poor physician-patient communication
6. Phillips <i>et al</i> (Phillips, Bartholomew <i>et al.</i> 2004) (2004)	Describe the epidemiology of negligent adverse events from primary care within a large US malpractice database	Claims analysed for negligent adverse events: their severity, causes, contributing factors, and medical conditions	Classification by measurement systems used within insurance database: 18 types of 'cause' and 7 types of 'contributing factors'	Causes: diagnostic error (34%), failure to monitor case (16%), improper performance (15%), medication errors (8%), delay in referral (4%), others (23%). Higher harm outcomes from provider communication error.

Table 2.4 Type 3 - Studies measuring other aspects of safety events in community settings.

Study	Aim of research	Data collection method	Measurement method	Major findings
1. Holden <i>et al</i> (Holden, O'Donnell et al. 1998) (1998)	Determine the pattern of deaths and potentially preventable factors in four practices	Audit of all deaths over 40 months using a standard data collection form	A series of preventable factors were determined by GPs at quarterly clinical meetings	An audit of deaths has educational value for GPs and is a source of ideas for service improvement and further study
2. Singh <i>et al</i> (Singh, Singh et al. 2005) (2005)	Develop a visual model for of error in primary care, using a 'systems engineering' approach	Computer based reporting system is suggested, using visual cues to indicate problem areas of system, and enter error data.	No error measurement method or classification described	No trials of method are described, theoretical findings are presented describing the components of the primary health care system.
3. Shaw <i>et al</i> (Shaw, Drever et al. 2005), Williams and Osborn (Williams and Osborn 2006) (2005-06)	Describe the implementation of a national incident reporting system for England and Wales	Reports from participating NHS Trusts sent electronically. System now capable of on-line anonymous reporting.	No error measurement method described, the reports were classified by 108 different types, not defined.	Majority of reported incidents from all sources were slips, trips and falls. Only 32 of nearly 30 000 reports came from one primary care trust.

2.8 Patient Safety Research in the Australian Community

Setting

2.8.1 Cost of medical errors in Australia

The financial burden of hospital based iatrogenic injuries have been analysed in Australia, and account for 2 to 3% of the annual budget of typical Australian community based hospital of 120 beds (Rigby and Litt 2000). It is very likely that financial savings would also result from the prevention of errors in primary care, where the majority of health care encounters take place, however as no studies to date have described frequencies of primary care errors, it is not possible to calculate this cost. However, Australia has been ahead of the rest of the world in research that has attempted to provide an overview of the type of errors encountered in general practice (Britt, Miller et al. 1997; Bhasale 1998; Bhasale, Miller et al. 1998).

2.8.2 The Incident Monitoring Technique applied to general practice

In 1993, the Commonwealth provided funding to test incident monitoring in six specialties, which included general practice. The resulting study's objectives were to apply the incident monitoring technique to the general practice environment, collect data on incidents and evaluate their possible causes, and examine potential harm relating to diagnostic processes. Bhasale and Britt have published results of the first 805 incidents reported between October 1993 and June 1995 (Britt, Miller et al. 1997; Bhasale 1998; Bhasale, Miller et al. 1998), and their analysis found that incident

monitoring is a useful tool for identifying sources of misdiagnosis and for implementation and assessment of quality improvement strategies.

‘Incidents’ were defined as an unintended event, no matter how trivial or commonplace, that could have harmed or did harm a patient. Between October 1993 and June 1995, 324 GPs participated at some time by invitation from membership lists of research and professional groups, and as volunteers.

The method used in this study was an anonymous written reporting system, which because of the possibility of identifying general practitioner participants, required an application for protection from subpoena under a Commonwealth Act of Parliament, the Health Insurance Act 1973. Participants were sent 10 copies of a four page incident report form, which included questions relating to patient and reporting GP demographics, and allowed free-text descriptions of incidents and structured responses for preventability, potential for harm, immediate consequences, predicted long-term outcomes, type of incident, contributing factors, mitigating factors and additional resource use (Britt, Miller et al. 1997).

Incidents were categorized as one of four major types, based on fixed choice responses from participants, and each type had varying numbers of sub-categories (in brackets). They were: pharmacological (16), non-pharmacological (6), diagnostic (4) and equipment related (3). Participants graded potential for harm using a five-point scale. Investigators used qualitative analysis to identify broad problem groups.

Altogether 805 incident reports were analysed, with 142 of the first 500 included in the exploration of harm relating to diagnostic processes. Pharmacological errors were most often reported by GPs. GPs reported that incidents were preventable 76% of the time, and that major harm occurred 17% of the time, with an additional 4% resulting in patient death. Investigators identified four broad problem groups from qualitative analysis of free-text responses: communication problems, procedural problems, clinical problems (due to human error) and external problems (outside the control of the GP).

The collection of incident forms was continued by the Research and Health Promotion Unit of the Royal Australian College of General Practitioners until June 1998, and of the total of 2582 reports received, 50% involved medication problems (Steven, Malpass et al. 1999).

The publications by Bhasale and Britt represent the first major study of a modified incident monitoring technique in a community setting, and provided the earliest evidence of the suitability of this method for subsequent similar studies on this subject. Anonymity and legal protections for reporting GPs provided a safe environment to encourage reporting. The methodology is an appropriate option for continuous use and quality improvement purposes. Although interview may elicit greater detail, completion of paper-based reports proved an effective and economical method to collect data.

There are a number of weaknesses in the method, which did not allow quantification of error types, as GPs may have been selective in their reporting. There was no way

of knowing how many reports were submitted per participant (not all forms were identified by a participant number), and participants did not complete the study in a defined time frame, sending in 10 reports from their point of enrolment. The findings are not able to be generalized as the sample was not randomly selected or representative. The measurement methods for classifying incidents may not be reliable, as there may be major inconsistencies in the way different GP participants classified their incident reports into the four main categories. In addition, the identification of problem groups by investigators appeared to have some degree of overlap (for example, 'procedural' problems included diagnostic incidents where "a correct diagnosis was rejected due to insufficient or incorrect examination", and at the same time 'clinical' problems included diagnostic incidents "where symptoms and signs were not recognized").

2.8.3 The critical incident technique applied to GP Registrars

Australian researchers also published some of the earliest work using the incident monitoring or critical incident technique with GP registrars. Two studies, conducted in 1992 and published in 1995 and 1996 aimed to obtain information on the experiences of GP trainees during their early training, and follow up with the same group after their advanced training to gauge changes in performance (Diamond, Kamien et al. 1995); (Sim, Kamien et al. 1996)

'Positive incidents' were events in their GP training that had made trainees feel good or competent; 'negative incidents' were events that had made them feel incompetent or unhappy with their performance. 39 GP trainees in Western Australia in their first term in 1992 were initially included, and follow-up was conducted with 18 of these

participants. The study method was a qualitative analysis of open ended interviews about positive and negative incidents describing competent or poor professional practices. In this respect it differed from other studies of 'error'. The study was not aimed at detecting harms to patients and so 'incidents' include non-patient safety related events such as poor relationships between GP and practice staff.

Investigators grouped critical incidents into 36 types, with the seven most commonly reported being described as: difficult patients, paediatrics, doctor-patient relationship, counselling skills, obstetrics and gynaecology, relationships with others involved in care, and cardiovascular disorders. Major skills associated with critical incidents were reported in three major categories: interpersonal skills, diagnostic skills, and management skills.

The studies found that the initial training is a crucial transition period for GP trainees, and analysis of incidents can be used by training programs to accelerate the learning process of doctors, and for planning undergraduate curricula. The trainees were found to have developed competence, confidence and reduced levels of anxiety with advancing experience. However, the findings are not readily able to be generalised as the study used a small non-representative sample with a low follow-up rate in the second study. The method did not allow anonymity of participants from investigators, and the 36 category classification has not been published.

2.8.4 The Primary Care International Study of Medical Error

This study (PCISME) provided a pilot for the TAPS study, and the Australian data and taxonomy published to its third level in the MJA in 2002 (Makeham, Dovey et al.

2002) provided the basic starting point for the development of the TAPS study and taxonomy. The PCISME taxonomy is presented from this publication in Appendix 4 of this thesis. Both the Australian and international results are described in this section of the thesis.

In 2000, the Robert Graham Centre of the American Academy of Family Physicians conducted a pilot study of medical mistakes reported by Family Physicians. This research informed the development of the 2001 pilot study, the Primary Care International Study of Medical Errors (PCISME). This study was an international collaboration of six first world primarily English speaking countries comprising Australia, Canada, England, the Netherlands, New Zealand, and the USA. There have been a number of publications describing different aspects of the study from a range of the participant countries (Makeham, Dovey et al. 2002; Beyer, Dovey et al. 2003; Woolf, Kuzel et al. 2004; Rosser, Dovey et al. 2005; Tilyard, Dovey et al. 2005)

Prof Michael Kidd and Dr Meredith Makeham coordinated the Australian arm of this pilot study in the Department of General Practice, University of Sydney. The methodology developed an electronic method for the anonymous collection of self-reported errors from general practitioners.

PCISME differed from previous Australian work in its focus on unwanted events, rather than ‘incidents’, whether or not they resulted in harm. The definition of an error used was:

Errors are events in your practice that make you conclude: “that was a threat to patient well-being and should not happen. I don’t want it to

happen again". Such an event affects or could affect the quality of the care you give your patients. Errors may be large or small, administrative or clinical, or actions taken or not taken. Errors may or may not have discernible effects. Errors in this study are anything that you identify as something wrong, to be avoided in the future.

Accordingly, the data related to any occasion, regardless of actual or potential outcome, in which any of the health care procedures or delivery systems used by participants and their patients deviated from their course, or were not capable of achieving the intended outcome. The data included the observations of general practitioners during their daily clinical practice of medicine, whether in practices, hospitals, patients' homes, nursing homes, or other sites of care delivery. The reports were therefore not necessarily of actions or omissions made by the reporting doctors themselves or affecting their patients. Reports could include incidents participants observed but involved other providers or patients. This definition attempts to incorporate as broad a range as possible of problems occurring in general practice. It allows participants to report not only on events that they consider to have been attributable to their own actions, but also unwanted occurrences that they note concerning patient care.

The methods used in PCISME also differed from previous primary care error research in that it allowed the development and testing of an on-line error reporting system, which comprised of an electronic form with free text and multiple choice fields, which was attached to a database for collection and analysis of results. The questionnaire was a series of closed and open-ended questions about the reported

error and the patients involved, including harm rating and suggestions for preventability. In order to use the electronic form, participants required a software package called Healix. Error reports were transmitted to a secure Healix server in London under encryption, and access to the database was protected and limited to the chief investigators in each country.

100 GPs and Family Physicians participated from all seven countries, with study group size varying between countries (8 to 23). A non-random sample of 20 general practitioners from the Sydney metropolitan region was enrolled in PCISME, and over a four month period contributed 139 electronic error reports.

A multilevel taxonomy based on previous work (Dovey, Meyers et al. 2002) was developed by the lead investigator based in Washington, USA (SD) working with the participant country investigators. Additional categories and sub-categories were created and/or changed as necessary. The resulting taxonomy contained 172 categories, with between 4 and 7 further levels in the measure's hierarchy.

There were similarities observed in the types of errors reported by all participants at the first and second levels of the measure (Makeham, Dovey et al. 2002).

Approximately 80% were 'process' errors and 20% 'knowledge and skills' (Beyer, Dovey et al. 2003). Physicians in most countries found the electronic method feasible. Altogether 166 qualitatively different prevention strategies were identified (Tilyard, Dovey et al. 2005).

PCISME represented the first attempt to develop a standard measure of patient safety events across different countries, although all countries represented in the study had ‘a similar concept of health care’(Makeham, Dovey et al. 2002). The study showed that it was possible to form a measure of patient safety that was comprehensible across different countries, cultures, and language bases. Only the first three levels have been described in the peer-reviewed literature (Makeham, Dovey et al. 2002) but the full measure is available on-line at www.errorsinmedicine.net/taxonomy/aafp.

There were a number of weaknesses in the study design. The number of participants in each country was small and they were not randomly selected or representative. It is unlikely that all possible patient safety events are captured by the measure. No statistical comparisons could be made of the different types of events reported in different countries. There were differences in the roles of primary care doctors in these different countries, and in the levels of computer use in community settings. Some participants (notably in Canada) were unable to submit reports via computer and had to use paper reports. This may have systematically altered the quality and/or content of their reports. The size of the resulting taxonomy may make it difficult for use other than as a descriptive tool.

2.9 *Limitations of this review*

Included in the literature review for this thesis were only research publications investigating the breadth of community based healthcare activity and its risks for patient safety. Excluded were studies that focused on a single bounded activity or cluster of activities, such as medications use or diagnosis. Only English-language papers were included.

This review produced papers mainly from the US, the UK, and Australia. The overwhelming body of published research about patient safety comes from this very limited set of countries, and so it is unlikely to address issues of importance to patient safety in many other countries – especially in the developing world.

2.10 Literature review conclusions

The key findings of this review are presented below in figure 2.6.

Figure 2.6 Key findings in the literature review of patient safety methods and measures in community settings.

- Incident reporting systems are reported as the method most often applied to safety event data collection in the community setting
- There is a large variation in definitions of ‘error’ and other related terms in patient safety research, and national or preferably international uniformity should be established to improve shared understanding of the subject
- Taxonomies of patient safety events in community settings are of two main types: ‘domain specific’ and ‘multi-axial’, and the appropriate classification will depend on the aims of the research, nature of the reporters and resources available to analyse data
- Despite a recognized poor ‘safety culture’ in health care, clinician attitudes to safety event reporting are positive provided the systems in place are non-punitive and educational, and support clinical care
- The National Reporting and Learning System established by the National Patient Safety Agency of the NHS is the only national safety event reporting system reported in the literature as being an anonymous secure system accessible to health care workers in community settings

As recently as five years ago, community based health care providers were more or less exempt from considerations about patient safety and they were explicitly excluded from the seminal patient safety reports from the US (Committee on Quality of Health Care in America 2000) and the UK (Chief Medical Officer, NHS 2000).

Since that time there has been a growing recognition of the increasingly urgent need

to reduce patient safety threats in community settings because most patients encounter formal health systems most often outside hospitals (Green, Fryer et al. 2001).

It has become generally accepted that a prospective reporting system is more suitable than retrospective record review for identifying safety events in primary care with a view to developing preventive strategies (Malpass, Helps et al. 1999) although this view has received little critical appraisal. The incident monitoring technique has been used in various forms in the majority of the studies identified, and was found to be an appropriate method for patient safety surveillance in community settings.

Although limited by background levels of computerization in the primary care setting, electronic databases and secure web-based reporting systems may offer the greatest potential for information gathering, data analysis, ease of access and protection from punitive repercussions for the reporters. Community based clinician attitudes to safety event reporting are generally positive, provided the systems in place are non-punitive and educational, and their institution on large scales would likely provide a mechanism to assist in improving the safety culture in community settings.

No literature was identified that used the technique of retrospective records review to discover threats to patient safety, apart from reviews of incident reports in one US study (Fischer, Fetters et al. 1997). Numerous barriers to this method could apply in a community setting, where a record of the breakdown in care that leads to a safety event might be spread amongst several different health care providers in different locations, unlike a hospital record, where multiple providers can contribute to a single set of patient notes. However, a study of this type has the potential to draw some

comparisons with hospital-based studies using this method (Brennan, Leape et al. 1991; Wilson, Runciman et al. 1995) and may warrant further exploration.

There have been calls for large scale reporting systems that would capture incidents and adverse events (Runciman, Edmonds et al. 2002), however only the National Reporting and Learning System established by the NHS in England and Wales has been reported in the literature to have achieved this on a national scale for health care professionals in the community setting. Overviews of its results have been published, but there have been no results of its findings regarding reports from the community setting, or aspects of its validity or acceptability in community settings published so far (Shaw, Drever et al. 2005; Williams and Osborn 2006).

There is a gap in the evidence on the types of methods that may better engage patients in safety reporting in community settings, and the value of their input in addressing different aspects of patient safety. Patients have been engaged successfully in qualitative research in community settings about perceived harm, but not in trials of safety event reporting systems, and this should be considered in future research planning.

Only seven studies that propose a measure (or taxonomy) for describing safety events in the primary care setting were identified. These classifications fell into two main categories: (1) 'multiaxial' taxonomies and (2) 'domain specific' or more simple classifications describing a single element of the safety event. The former incorporate a number of different aspects about a safety event into its coding, such as the nature of the event, associated harm, patient and reporter factors, or cognitive factors in its

causation. The domain specific taxonomies identified focus mainly on the nature of the event in categories with a mixture of clinical and administrative titles.

Not all of the taxonomies in the literature proposed for community settings have been tested, and in those that have, there are major limitations to consider with respect to their validity and comprehensibility. None of the studies attempted to test the reproducibility of their proposed taxonomies across different analysts or primary care clinicians. Of all the studies identified discussing safety events in primary care, only one used a representative sample (Makeham, Kidd et al. 2006). Although a taxonomy developed to cross disciplines has been proposed (Chang, Schyve et al. 2005), it also remains untested with primary care clinicians.

The research into patient safety in community settings generally spans little more than a decade, although there is an extensive literature easily interpretable as relevant to patient safety in more bounded areas such as medications use and diagnosis. The scope of this review has not included a rigorous analysis of these specific safety topics, which may provide further insight into methods and measures of relevance to patient safety events in community settings.

A limitation of attempting to combine the findings of various studies is that there is a large variation in definitions of 'error' and other related terms in patient safety research. It would therefore be useful if national or preferably international uniformity was established amongst researchers and health policy makers.

Taxonomies of patient safety events in community settings are mainly in developmental stages, and much further testing is required in the field.

There are relatively few countries engaged in patient safety research in community settings, and the review was limited by the predominantly ‘Western’ nature of the published scientific literature. Attempts to increase the efforts at an international level should ideally consider ways to engage a broader range of communities and health care settings, including developing countries and different cultural groups.

This review supports the conclusion that prospective reporting of threats to patient safety made by healthcare providers in community-based settings is readily achievable. Local, institutional, national, and international reporting systems have all been successfully trialled. Reports made this way will identify classes of risk to patient safety. This reporting should probably be facilitated through electronic systems and analysed using multi-axial or domain-specific taxonomies of event type, combined with other information that a sophisticated reporting and learning system is able to collect about the safety event.

There are challenges in many countries to instituting national reporting and learning systems, but developments on the international scene such as the creation of the WHO World Alliance of Patient Safety are improving the research effort in the subject of patient safety in community settings, and the benefits to health systems and patients should follow.

3 Methods

3.1 Overview

This section of the thesis addresses the methods by which the four major aims of the TAPS study outlined earlier were met. A group of general practitioners (GPs) submitted anonymous online reports about any errors that they noted over a twelve month period commencing in October 2003, and the basic design and various ethics and other approvals are described in sections 3.2 to 3.6. The design of the web-based reporting system had a number of technical requirements, which are addressed in sections 3.7 and 3.8. The process of sampling the group of GPs and their consent and education on how to use the TAPS reporting system is described in section 3.9, and the method of collecting their patient visit data is described in section 3.10. The methods used to determine the incidence of reported error are presented in section 3.11, and finally the methods used to develop the TAPS taxonomy of safety events and determine their proportions are described in section 3.12 and 3.13. Sections 3.14 to 3.18 describe the methods applied to analyse other features of the reported errors, including patient related factors, event locations, associated harm, preventability, perceived frequency of reported error types, and the final section 3.19 discusses the participant feedback interview.

The methods of the TAPS study have been previously published in the peer reviewed scientific literature, relating to general study design, incidence calculations, taxonomy development, proportions of error types and coder agreement (Makeham, Kidd et al. 2006; Makeham, Stromer et al. 2007), and these papers are presented in Appendices 6 and 7.

3.2 NHMRC Project Grant funding, Ethics approval and consent process

The TAPS study won a National Health and Medical Research Council (NHMRC) Primary Health Care Project Grant for the years 2003 to 2006, which funded direct research costs and research assistant staff salaries associated with the study. In addition, the Chief Investigator (Meredith Makeham) was awarded an NHMRC research scholarship to undertake the study.

The TAPS study ethics approval was obtained from the University of Sydney Human Research and Evaluation Ethics Committee. The Information and Consent Form appears as Appendix 2 of this thesis. Consent from all general practitioner participants was obtained in person at their practices in metropolitan and rural regions of NSW by a member of the study team. Participants were given an electronic demonstration of the TAPS web-based error reporting system at this time.

3.3 Qualified Privilege granted by NSW Health Minister

The Chief Investigators of the TAPS study (Dr Meredith Makeham, Prof Michael Kidd, Clinical Professor Michael Mira and Dr Chris Cooper) applied for and were granted Qualified Privilege under Division 6B of the Health Administration Act 1982 and the Health Administration Regulation 2000, which provided protection from subpoena of TAPS committee meeting minutes by the NSW State Minister of Health (at this time, The Hon. Mr Morris Iemma).

The provision of qualified privilege for quality assurance committees is designed to encourage health care professionals to participate in quality assurance activities by providing for:

- the confidentiality of documents and proceedings of the Committee
- the protection of those documents and proceedings from being used in legal actions
- the protection from liability and indemnity for present and former members, of the Committee, who were acting in good faith in carrying out their responsibilities.

There is clearly a strong public interest in ensuring that the health system provides high quality health care. The rationale behind the provision of these privileges is that if reviews of health services are impeded by the lack of participation by health care professionals then there is a public interest need to remove the known barriers to their participation. This is the basis for arguing that there is a public interest in maintaining the confidentiality of information generated by quality assurance committees, if that confidentiality is essential to the participation by health care professionals. This public interest should however, be balanced against the community's interest in accessing information about health services (NSW Health 2007).

The TAPS committee was required when seeking qualified privilege to show that:

- the public interest in gaining health care professionals participation outweighed the community's interest in accessing information, and
- that there would be an improved standard of patient care arising from the Committee's activities if it was able to operate under a guarantee of privilege.

3.4 RACGP Audit Activity Approval

The acquisition of QACE points is mandatory for Australian general practitioners (GPs) who wish to remain on the vocational register, and GPs require 60 group 1 points within a triennial cycle. Application to the Royal Australian College of General Practitioners (RACGP) was made by the chief investigators of the study and the TAPS study was approved as an audit activity. TAPS study participants who wished to participate were granted 30 Group 1 Quality Assurance and Continuing Education (QACE) points for their completion of a twelve month learning cycle that coincided with the twelve month reporting period. The award of QACE points was optional for participants and had no bearing on their general involvement in the study.

In order to be eligible for the 30 QACE point award, the TAPS participants who requested to be a part of the additional audit activity had to complete a baseline reflective questionnaire prior to the commencement of reporting. They received a summary of the TAPS activity results at the end of the first and second six months and completed a questionnaire at each point detailing their learning as a result of the study. A final questionnaire was completed in which participants reflected on what they had learnt as a result of their participation, completing a learning cycle.

3.5 Definition of error in general practice used

The definition of 'error' used was derived from previous work (including that undertaken by Meredith Makeham) (Dovey, Meyers et al. 2002; Makeham, Dovey et al. 2002; Woolf, Kuzel et al. 2004a; Tilyard, Dovey et al. 2005) and attempts to incorporate the broadest possible range of problems that may be encountered. The

error may be attributable not only to the reporter's actions, but also other unwanted occurrences concerning patient care:

“Errors are events in your practice that make you conclude: *‘That was a threat to patient well-being and should not happen. I don’t want it to happen again’*. Such an event affects or could affect the quality of care you give your patients. Errors may be large or small, administrative or clinical, or actions taken or not taken. Errors may or may not have discernable effects. Errors in this study are anything that you identify as something wrong, to be avoided in the future.”

This definition was the most appropriate to use in the TAPS study as it had already been tested in association with a very similar questionnaire in the pilot study (Dovey, Meyers et al. 2002; Makeham, Dovey et al. 2002; Woolf, Kuzel et al. 2004a; Tilyard, Dovey et al. 2005), and participants had displayed a good understanding of the term (Makeham, Dovey et al. 2002), although more recent suggestions of definitions of error, harm and safety have been discussed in the literature review (Runciman 2006; WHO World Alliance for Patient Safety 2006), with suggestions that common meanings are adopted by researchers.

3.6 TAPS study error questionnaire

The questions contained within the TAPS questionnaire were based upon those used in the pilot study, *PCISME* (Makeham, Dovey et al. 2002). The difference from the pilot study was the addition of Question a) relating to the RRMA area of the practice, which allowed some sub-group analysis of error reporting rates based upon practice location further discussed in section 3.11. The questions are shown below in table 3.1:

Table 3.1 Error questionnaire used in the TAPS study.

Question	Answer format
a) What is the RRMA area of your practice?	RRMA 1, 2-3 or 4-7
b) Is the problem related to a specific patient?	YES/ NO
c) How well do you know the patient?	5 point Likert scale
d) What is the patient's age?	Free text
e) What is the patient's sex?	MALE/ FEMALE
f) Is the patient from a non-English speaking background?	YES/ NO
g) Is the patient of Aboriginal or Torres Strait Islander descent?	YES/ NO
h) What happened? Please consider what, where and who was involved.	Free text
i) What was the result? Please think about actual and potential consequences.	Free text
j) What may have contributed to this error? Please consider any special circumstances.	Free text
k) Where did the error happen? Choose all that apply from <i>Office or surgery, Nursing home, Hospital, Patient's home, Telephone contact, Emergency Room, Laboratory, Pharmacy, Radiology</i>	Check a box or boxes: 9 choices
l) To your knowledge, was any patient harmed by this error?	YES/ NO
m) If yes, how would you rate the seriousness of this harm?	5 point Likert scale
n) How often does this error occur in your practice? First time, Seldom 1–2 per year, Sometimes 3–11 per year, Frequently >1/month	Check a box: 4 choices
o) What could have prevented this error? Please consider what could be done to prevent similar episodes from happening in the future.	Free text
p) Other comments?	Free text

3.7 The TAPS web-based error reporting system

3.7.1 Major requirements of the TAPS reporting system

In order to collect sensitive information on threats to the safety of their patients from a group of Australian general practitioners (GPs), the following requirements of the system were established:

- Of the utmost importance was that participant GPs and any health workers or patients involved in reports should have their anonymity protected
- The system should allow ease and flexibility for reporting GPs who wish to submit reports either at home or at work, check on numbers of reports submitted, contact the investigators and access useful links to other information sources

A Sydney-based private internet service providing company (ISP) called L&P Net Solutions Pty Ltd was engaged to develop the website and reporting system based on the system and security requirements developed by the candidate that are outlined in this section.

3.7.2 The TAPS website security measures

There were a number of considerations taken into account when establishing that the TAPS reporting system would ensure privacy for participants. Figure 3.1 displays the various website security measures described in this section. A website security engineer was consulted in the early stages of planning, and the system was designed to follow internationally recognised information security standards for highly sensitive information. In addition to other techniques outlined below, a service level agreement (SLA) was entered into with the web hosting company. This SLA enforced

a required level of vigilance on the part of the web host company regarding the security of the system. This ensured server patches were kept up to date, intrusion detection logs were checked, and physical security was maintained.

In a system such as the one proposed there are three major risks to the security of participant data. The first is that the data may be intercepted while in transit between the GP and the system, the second is that there may be unauthorised access to the data stored on the system, and the third is that the anonymity of survey participants may be compromised. These concerns are addressed below.

3.7.2.1 Data interception risk

The data interception risk was mitigated by employing industry standard encryption between the survey participant's computer and the system. The encryption is built into the operating system on all standard computers and does not require any configuration on the part of the user. The encryption was enabled automatically when the participant began undertaking a report, and if for any reason the participant's computer was unable to provide this encryption the system would not then allow them to continue.

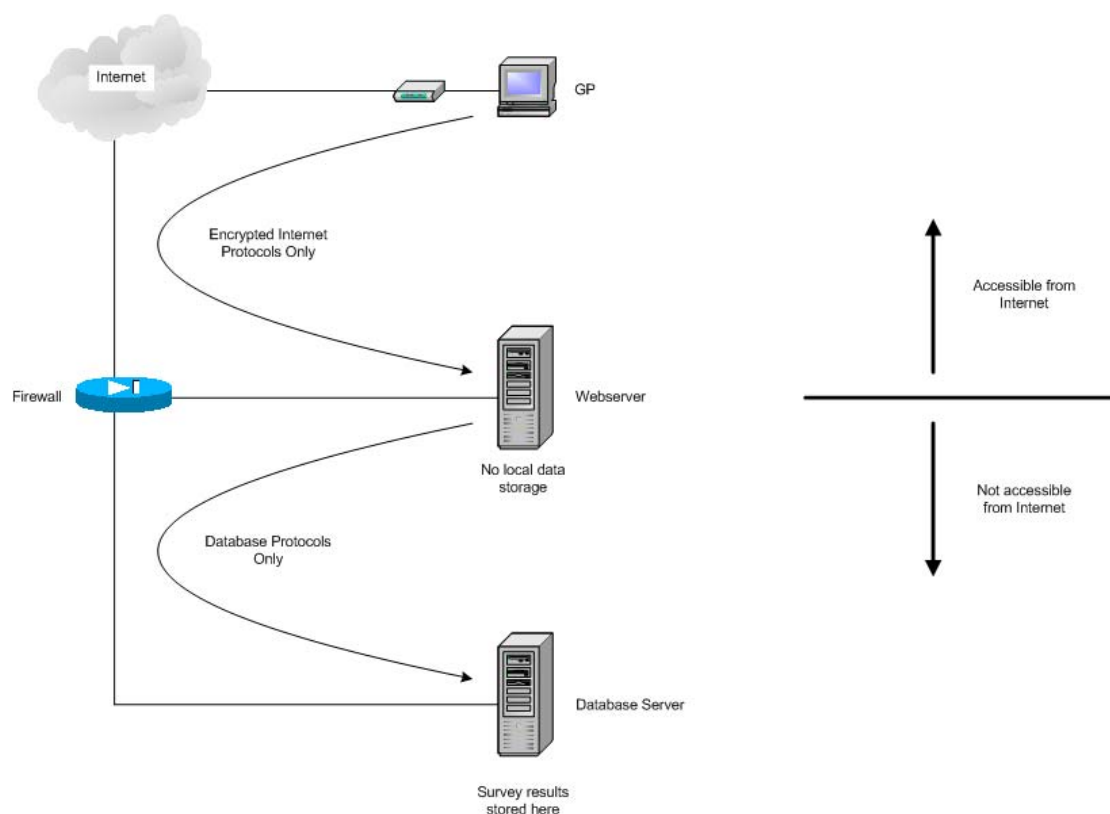
3.7.2.2 Unauthorised access risk

The unauthorised access risk was mitigated by splitting the system into two parts - a web server and a database server. The web server was accessible from the internet and did not store any participant data. The database server was accessible only from the internal network of the web hosting company, and this is where the participant data was stored. Access to the database server required a password. Both systems were protected by firewalls and both were supplied with intrusion detection capabilities.

3.7.2.3 Compromise of anonymity risk

The compromise of anonymity risk was mitigated by participants being identified in the reporting process with a personal identification number (PIN) of their own choosing. This PIN was known only to the participant. Thus the identity of participants was protected even in the highly unlikely event that the system security was compromised. In addition, the web server logs were purged on a periodic basis to prevent reconstruction of session information.

Figure 3.1 Illustration of the TAPS electronic system architecture displaying security measures.



3.7.3 Contents of the TAPS website

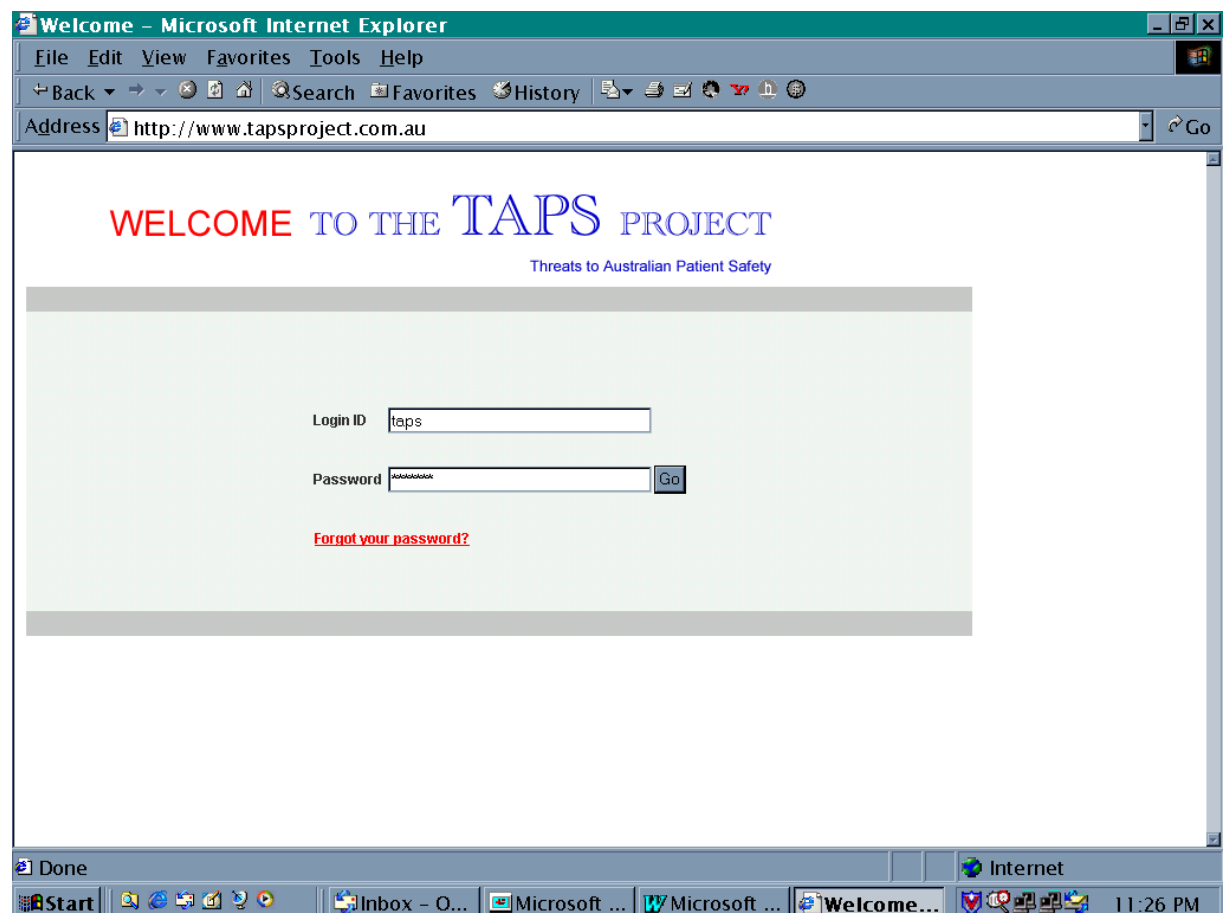
The TAPS website structure consists of two main areas, being the online area accessible to participants granted password access, and the database management

system, accessible only to Dr Meredith Makeham and members of the research team.

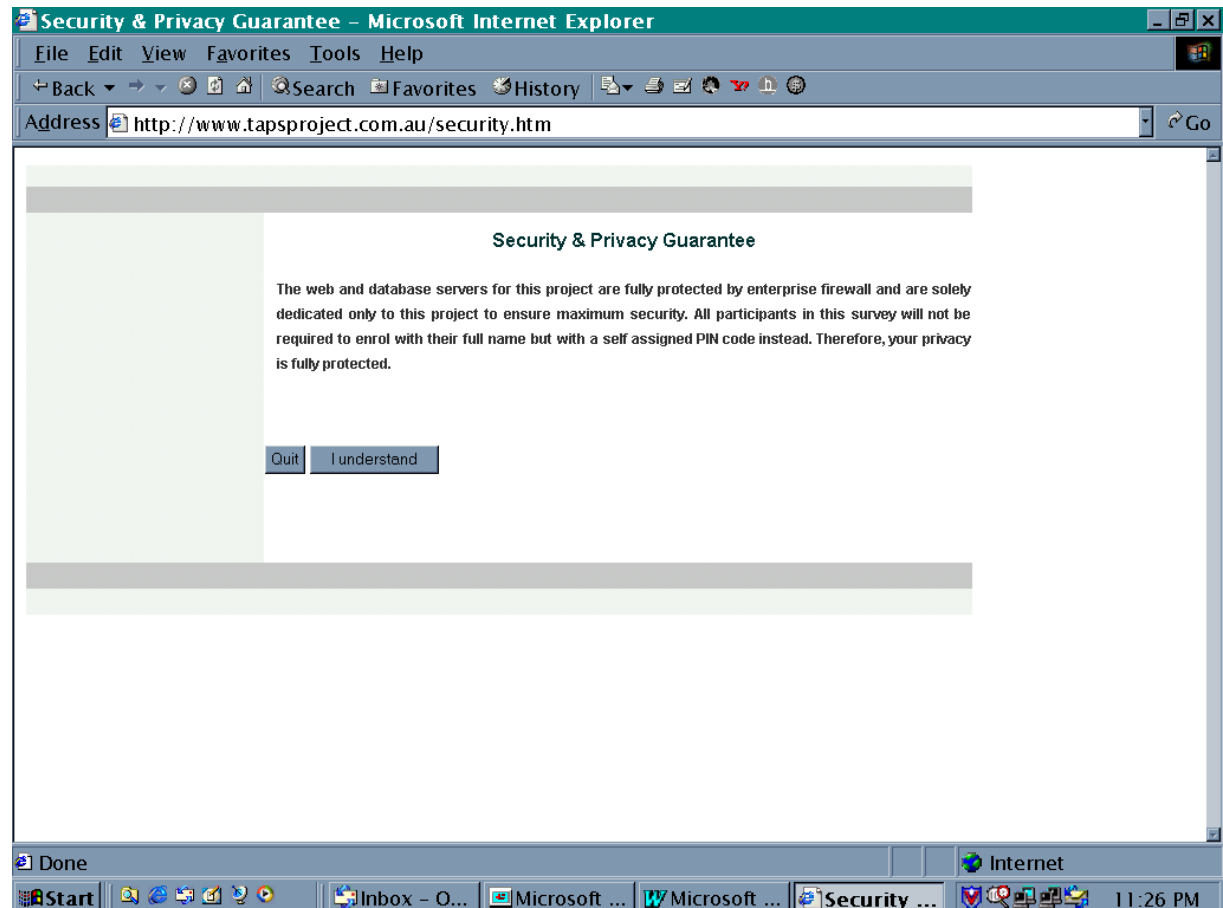
This section of the thesis describes the online area.

3.7.3.1 TAPS Website access and security pages

The first step was for participants to go to www.tapsproject.com.au and once at this location, a user name and password was required to proceed to the homepage, which was given to all participants with a demonstration of the site after they had consented to participate in the study. There was also a button on this page entitled ‘Forgotten your password?’ which if activated allowed the participant to send a query directly to the investigators who could discuss the access process by telephone after verifying the authenticity of the sender. These queries were followed up within 24 hours of receipt by the Chief Investigator (Meredith Makeham) or Project Manager (Geraldine Card).



Once successfully through the access page, the participant was required to read and acknowledge their understanding of a security and privacy statement:

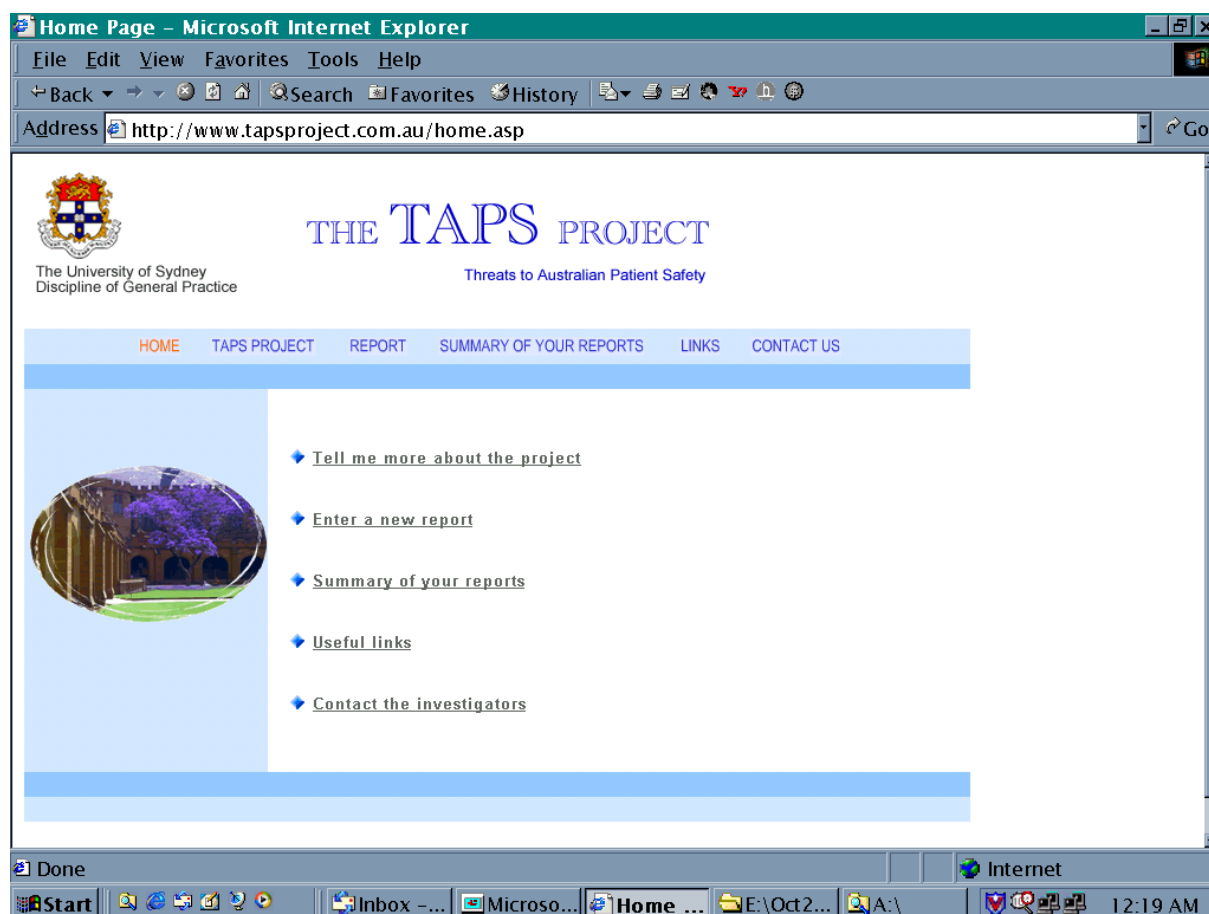


3.7.3.2 TAPS Website home page

The home page of the website had five different sections available to the user, being more information about the study, the TAPS questionnaire and report submission area, an area to contact the investigators, an area to check on the number of reports that had been submitted, and an area with useful links to online education resources.

‘Tell me more about the project’ was a page with the general aims and an outline of the study methods. The page entitled ‘summary of your reports’ was used by

participants at any point in the study if they wished to view a list of submitted reports with time and date of submission by entering their PIN. 'Useful links' were websites that the investigators knew to contain medical guidelines or library resources, and 'Contact the investigators' allowed the participants to send an email enquiry directly to the investigating team. Images of the home page and samples of these sections follow:




TAPS Project – Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites History Print Mail News RSS Feeds

Address <http://www.tapsproject.com.au/taps.asp> Go



The University of Sydney
Discipline of General Practice


THE TAPS PROJECT

Threats to Australian Patient Safety

HOME TAPS PROJECT REPORT SUMMARY OF YOUR REPORTS LINKS CONTACT US

Investigating Threats to Australian Patient Safety in General Practice

The TAPS Project



Project Team

Professor Michael Kidd, Dr Meredith Makeham, Dr Chris Cooper, Professor Michael Mira, Professor Deborah Saltman, Emeritus Professor Charles Bridges-Webb, Ms Geraldine Card

Significance of the TAPS (Threats to Australian Patient Safety) Study

- This will be the first major study of errors in General Practice which is designed to obtain frequency data for errors in Australia, and will also be the first project in the world to do so.

Done Internet


Start | | | | | | | | 12:25 AM

Reports – Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites History Print Mail News RSS Feeds

Address <http://www.tapsproject.com.au/reports.asp> Go



The University of Sydney
Discipline of General Practice

THE TAPS PROJECT

Threats to Australian Patient Safety

HOME TAPS PROJECT REPORT SUMMARY OF YOUR REPORTS LINKS CONTACT US

Check Your Reports Submitted

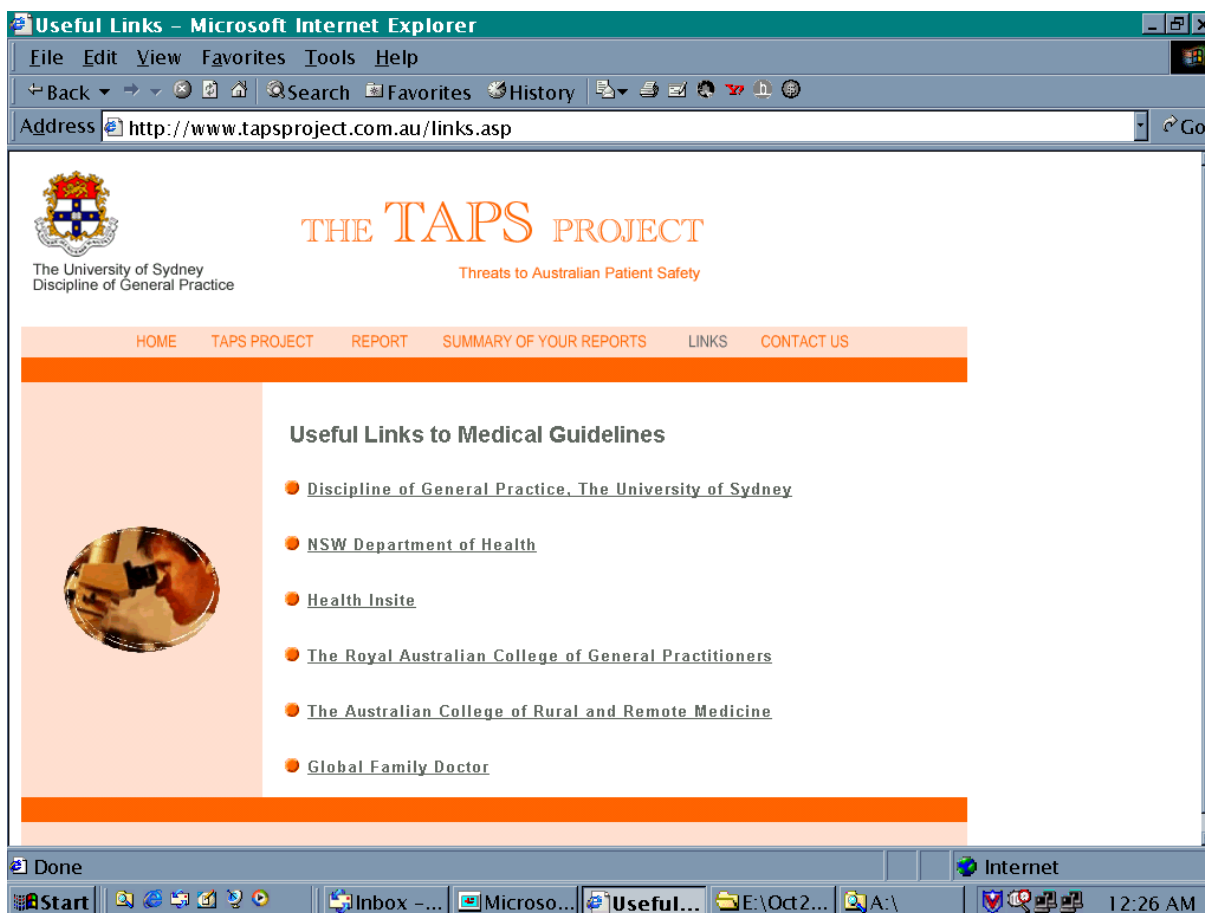
Please type in your self chosen PIN ID and then click Submit.

PIN ID



Done Internet

Start | | | | | | | | 12:23 AM

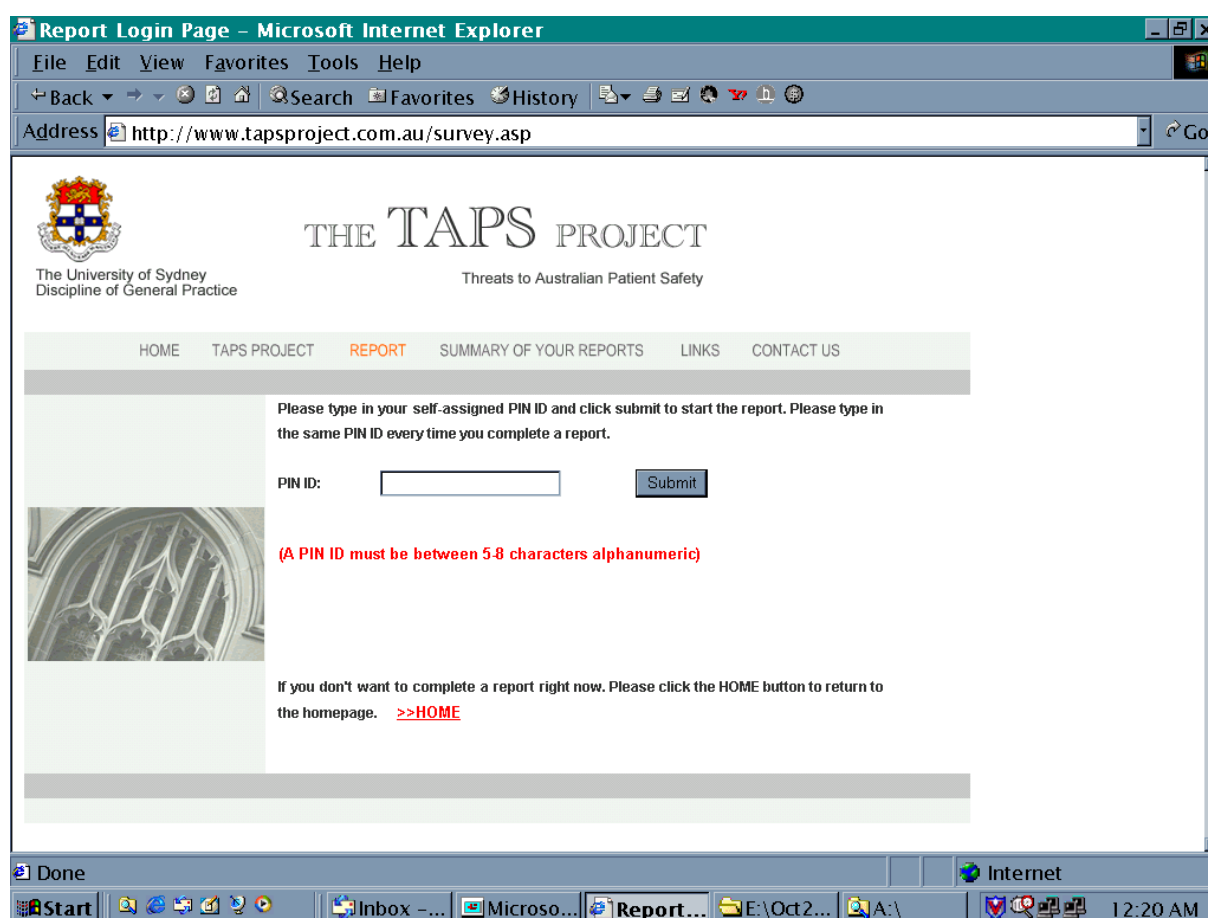


3.7.3.3 TAPS Website error reporting pages

From the home page of the TAPS website, the participant could enter the section entitled “Enter a new report”. Participants were told to choose a Personal Identification Number (PIN) for the duration of the study, with any combination of numbers or letters between 5 and 8 characters. They were advised to choose something easily memorable, but not identifiable. Investigators took no part in assigning the PIN, and had no knowledge of individual participant’s choices. This further protected the anonymity of participant GPs, however in the event of someone forgetting the original PIN they had chosen, investigators were unable to assist in recovering the original PIN. Participants were advised that forgetting their original

PIN would not prevent them from continuing in the study, but asked if this occurred, to please choose another and inform the investigators that they had forgotten their original PIN and would be continuing with a different one, to assist in interpretation of results.

The first screen in 'Enter a new report' is the PIN entry page, shown below:




Following the PIN entry page, the participant was led through several pages of reporting as per the error questionnaire, shown below in sequence:

Report Page 1 - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites History Print Mail RSS News

Address <http://www.tapsproject.com.au/survey1.asp> Go



THE TAPS PROJECT

The University of Sydney
Discipline of General Practice

Threats to Australian Patient Safety

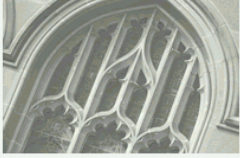
TAPS Report

a) What is the RRAMA area of your practice? [HELP](#)

1

2-3

4-7




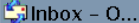



b) Is the problem related to a specific patient?

Yes

No

Cancel Next

Done Internet


Start |  |  |  |  |  | 11:27 PM

Report Page 2 - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites History Print Mail RSS News

Address <http://www.tapsproject.com.au/survey2.asp> Go



THE TAPS PROJECT

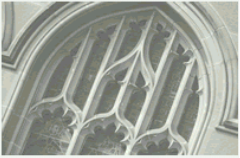
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Discipline of General Practice

Threats to Australian Patient Safety

TAPS Report

c) How well do you know the patient?

I have never seen this patient before and I am not familiar with his/her health problems	1	2	3	4	5	I am very familiar with this patient and his/her health problems
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	




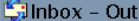



d) What is the patient's age?

e) What is the patient's sex?

Male

Female

Done Internet


Start |  |  |  |  |  | 4:34 PM

Report Page 2 – Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites History Print Mail News RSS Feeds

Address <http://www.tapsproject.com.au/survey2.asp> Go



e) What is the patient's sex?

Male

Female

f) Is the patient from a non-english speaking background?

Yes

No


g) Is the patient of Aboriginal or Torres Strait Islander descent?

Yes

No

Cancel Back Next

Done Internet

Start  Inbox - Out... Report Pa... A:\ Microsoft P... 4:34 PM

Report Page 3 – Microsoft Internet Explorer

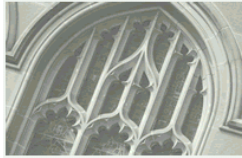
File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites History Print Mail News RSS Feeds

Address <http://www.tapsproject.com.au/survey3.asp> Go

TAPS Report


h) What happened? Please consider what, where and who was involved.



i) What was the result? Please think about actual and potential consequences.

j) What may have contributed to this error? Please consider any special circumstances.

Done Internet


Start  Inbox - Out... Report Pa... A:\ Microsoft P... 4:36 PM

Report Page 4 – Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Search Favorites History

Address http://www.tapsproject.com.au/survey4.asp



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k) Where did the error happen? Choose all that apply from :

- Office or surgery
- Nursing home
- Hospital
- Patient's home
- Telephone contact
- Emergency Room
- Laboratory
- Pharmacy
- Radiology
- Other



l) To your knowledge, was any patient harmed by this error?

Yes

No

Done Internet


Start Inbox - Out... Report Pa... A:\ Microsoft P... 4:36 PM

Report Page 5 – Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Search Favorites History

Address http://www.tapsproject.com.au/survey5.asp



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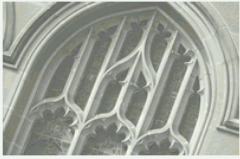
THE TAPS PROJECT

Threats to Australian Patient Safety

TAPS Report

m) If yes, how would you rate the seriousness of this harm?

Not serious at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Extremely serious
	1	2	3	4	5	



Cancel Back Next

Done Internet

Start Inbox - ... Report... A:\ Microso... 4:45 PM

Report Page 6 – Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites History Print Refresh Stop

Address <http://www.tapsproject.com.au/survey6.asp> Go

TAPS Report

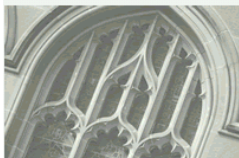
n) How often does this type of error occur in your practice?

First time

Seldom 1-2 per year

Sometimes 3-11 per year

Frequently >1/month



o) What could have prevented this error? Please consider what could be done to prevent similar episodes from happening in the future.

p) Other comments?

Done Internet

Start | Inbox - Out... | Report Pa... | A:\ | Microsoft P... | 4:37 PM

Report Page 7 – Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites History Print Refresh Stop

Address <http://www.tapsproject.com.au/survey7.asp> Go



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Threats to Australian Patient Safety

TAPS Report

Thank you for completing the questionnaire. If you would like to review your responses, use the BACK button below. Please press SUBMIT to send your completed report.



Back Submit

Done Internet

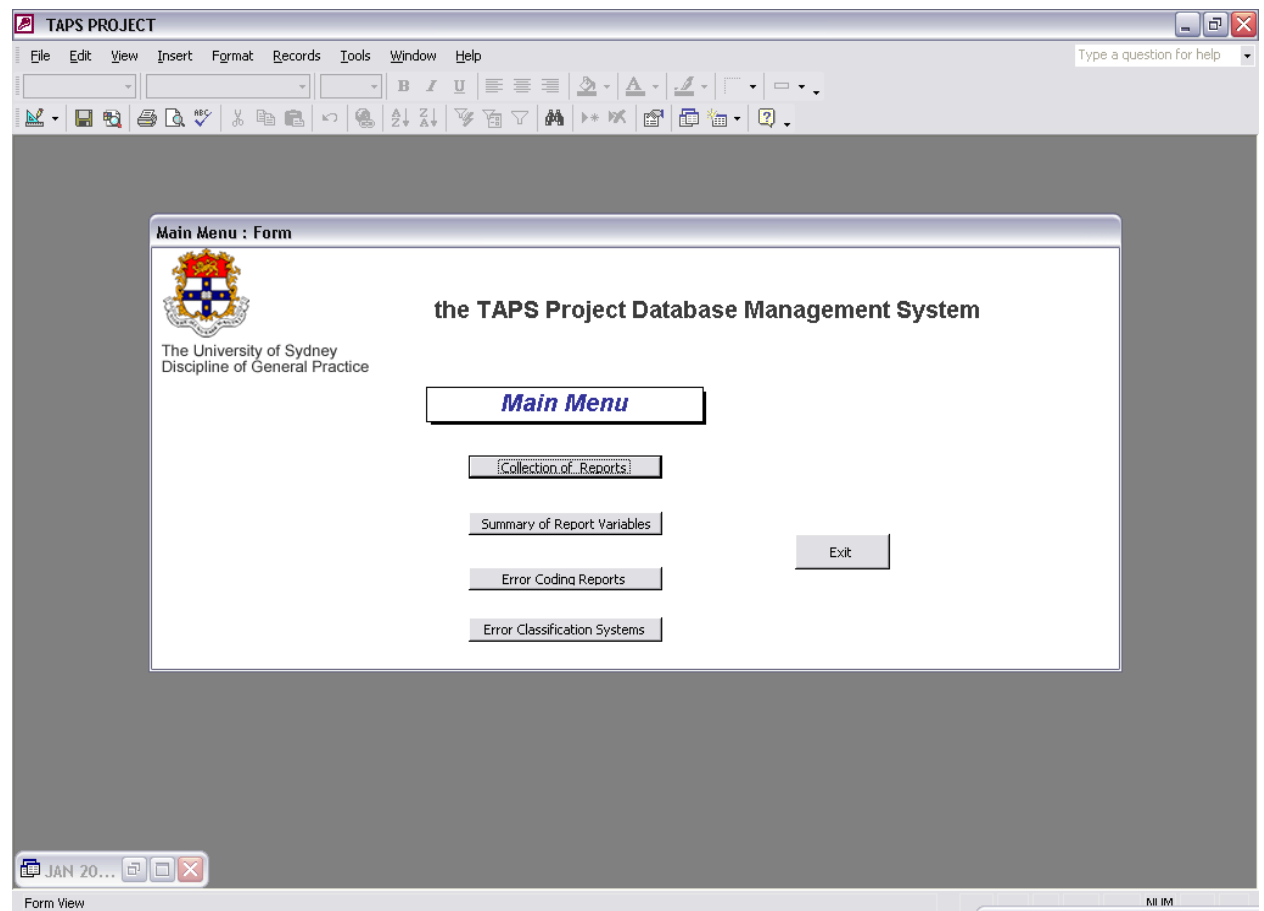
Start | Inbox - ... | Microso... | Report... | E:\Oct2... | A:\ | 12:22 AM

Only the PIN and RRMA data entry were required fields, and participants were able to freely move forwards and backwards through the questionnaire if desired. On hitting submit, a confirmation page appeared to advise of transmission success.

3.8 The TAPS database management system

Behind the website user interface, a specific Microsoft Access programme was designed by the Chief Investigator (MM) to manage the TAPS data, entitled the TAPS database management system. Reports that were received by the Internet Service Provider (ISP) were housed within this system, and transferred to the Chief Investigator (MM) in this format for further analysis and management each month.

The database management system was built with several levels of functions, and was designed with capabilities to analyse the data beyond the scope of this thesis. It is only available to the study researchers, not to GP participants. The front menu had a series of four main sections to choose from, being: collection of reports, summary of report variables, error coding reports and error classification systems, which appear in the following screen capture:



3.8.1 Collection of reports

Within this section, the user is able to look at the contents of all reports, search through them and enter the coding area for each one. There is a sub-menu with two further options, being 'view reports' and 'search reports'.

3.8.1.1 View reports

In 'view reports', it is possible to look at the complete set of reports in the system, and in addition the database allows the user to specify a time period by month if desired.

The viewed report displays all of the participant entered data in a single screen, an example of which is shown in the following screen:

TAPS PROJECT

File Edit View Insert Format Records Tools Window Help

Type a question for help

Report Details

Report Detail

NO#: 148

Survey Time: 25/11/2003 3:05:35 PM

PIN: calt1

RRAMA Group: 1

QB: Related to a patient? Yes

QC: How well know the patient? 4

QD: Patient age 35

QE: Patient Sex F

QF: Patient fr a non-English speaking background? Yes

QG: Patient is Aboriginal / Torres Straight Islander? No

QH: What happened?
Patient had heavy flooding bleeding. Was told by frined this was OK so continued to bleed for 4 more days. Seen by another GP who started her on oestrogen as felt the bleeding was related to Implanon and so needed balance with oestrogen. Finally rang me on day 7 of bleeding and had bled down to a Hb of 6.6

QI: What was result?
Patient was put on PrimolutN and ultrasound organised which confirmed bleeding was secondary to unstable endometrial lining. Bleeding settled within 12 hours of starting the PrimolutN

QJ: What may have contributed to this error?
GP unaware of the need to stop the bleeding with progesterone despite it being due to imbalance between the oestrogen and progesterone.

QK: Where did the error happen?

Office / surgery	1	Telephone contact		Radiology	
Nursing home		Emergency Room		Other	
Hospital		Laboratory			
Patient's home	1	Pharmacy			

QL: Patient was harmed? Yes

QM: The seriousness of this harm 3

QN: How often does this error occur? 1-First Time 2-Seldom 1-2 /y 3-Sometimes 3-11 /y 4-Frequently >1/m 2

QO: What could have prevented?
1. Pateint awareness that if they think something is wrong to present evenif someone else tells them it is OK.
2. Education regarding how to manage heavy menorrhagia.

QP: Other comments
Luckily patient presented before bleeding to a level where she required transfusion and Hb can be increased with oral Fe

Error Coding First Record Previous Record Next Record Last Record Print Close

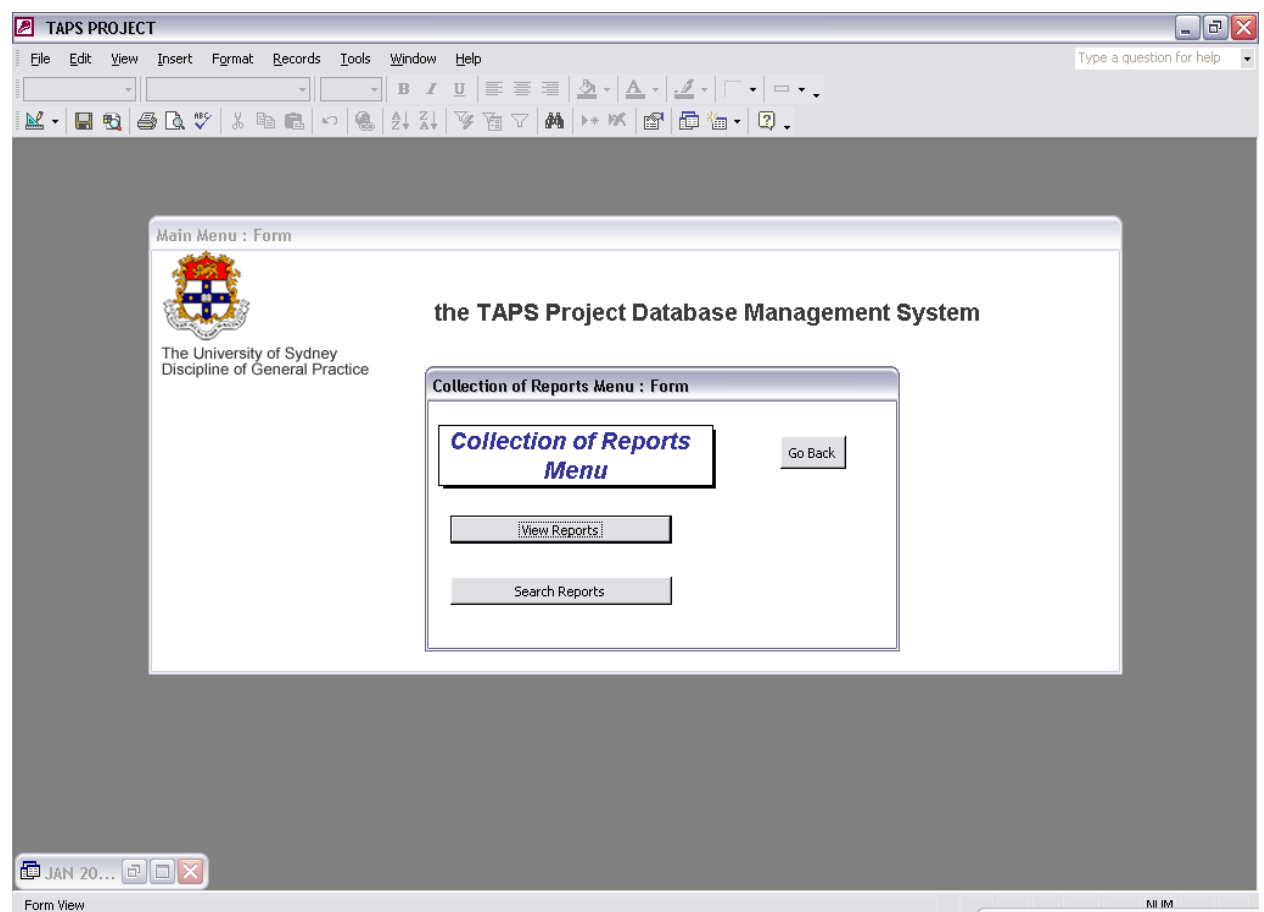
Record: 148 of 737

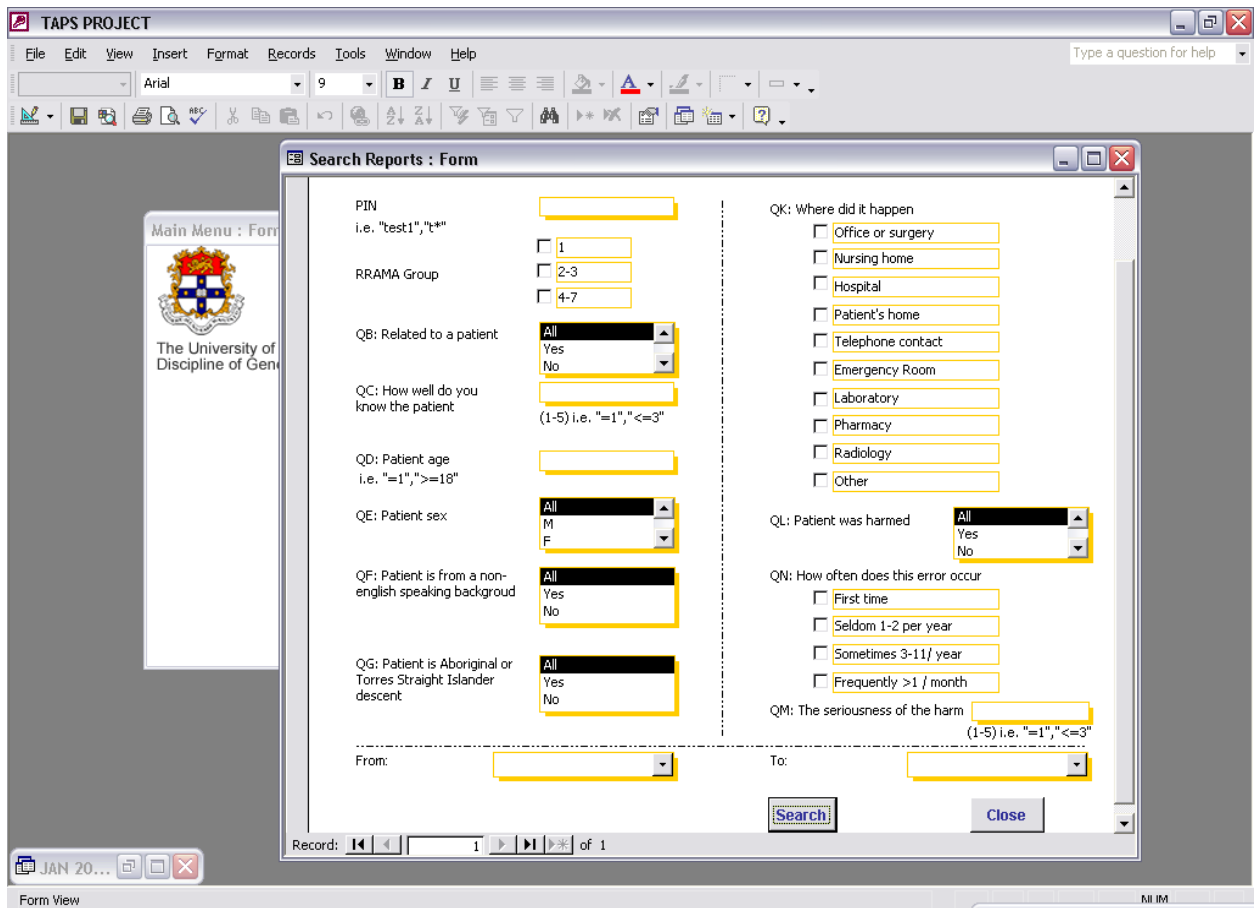
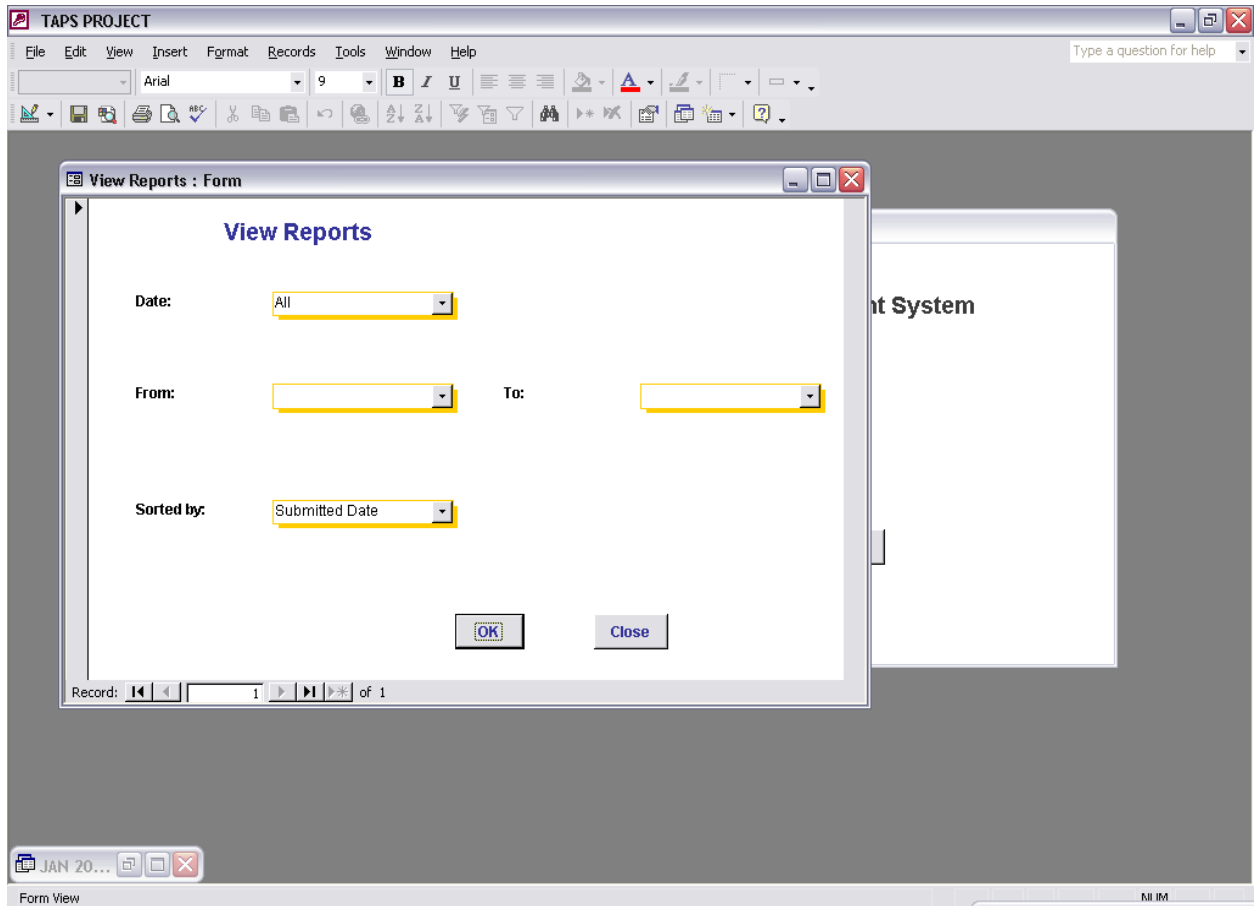
Form View NUM

The report detail includes the date and time at which it was submitted to the database in addition to the answers to the TAPS questionnaire entered by the participant, and the group of records can be quickly navigated using the forward and back arrows on the bottom left of the screen. There are also a series of short cut keys along the bottom of the display, including the 'error coding' button on the bottom left. This takes the user to a page that is designed to record the classification information about each record, and will be described in a later section.

3.8.1.2 Search reports

‘Search reports’ gives the user an option of searching for specific subsets of reports, whereby any of the variables that the participant GP has entered in answer to the closed TAPS questions may be used as search parameters. The system allows up to five independent parameters to be used simultaneously. One of the possible search parameters also includes the participant PIN, enabling the user to pull up a set of reports from an individual PIN that can be typed into the search screen. Screen captures of the ‘view’ and ‘search’ functions appear below:

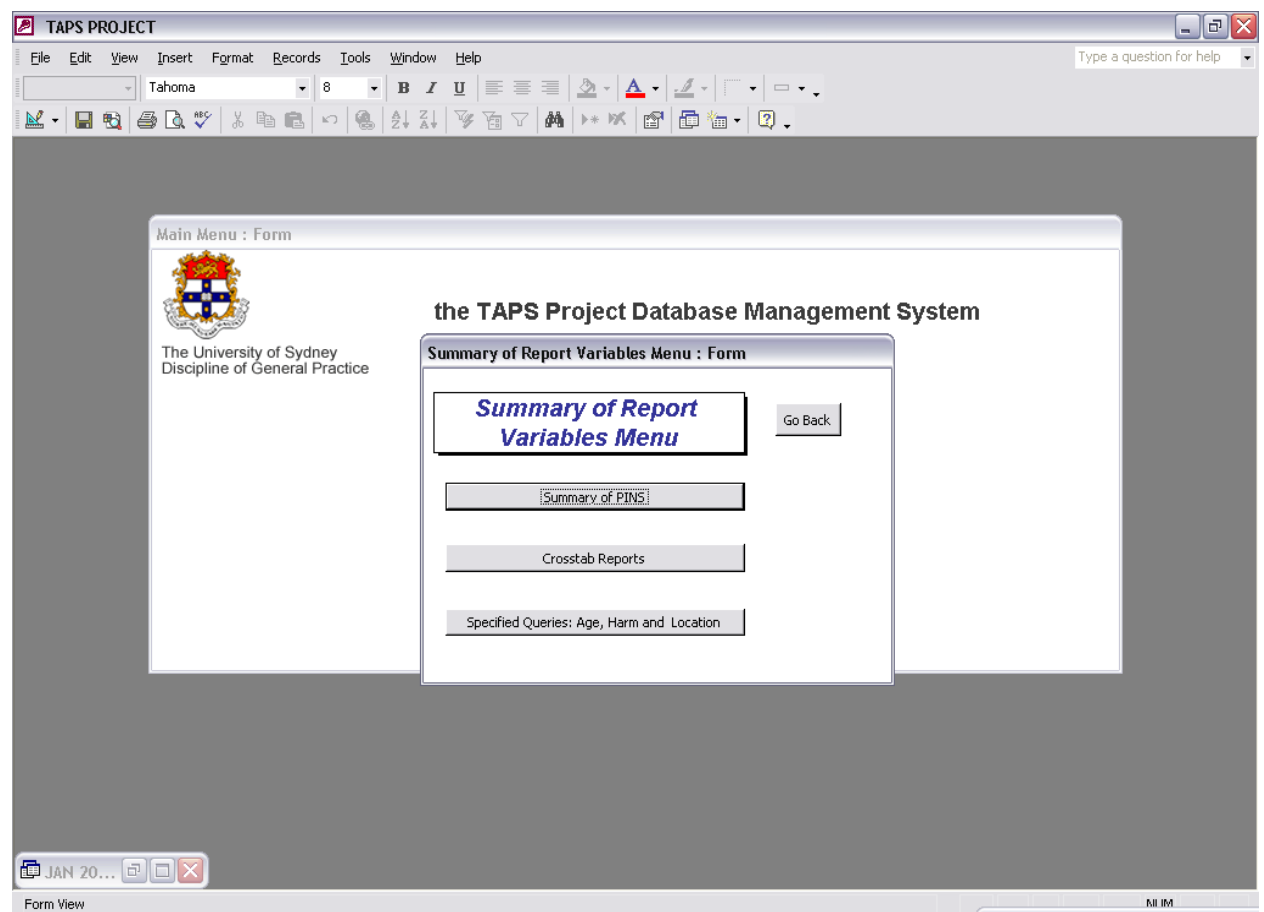




3.8.2 Summary of report variables

This section allows the user to view the set of PINs appearing on reports, to create a series of two by two tables using reports variables, and to run a series of specific queries about reports relating to patient's ages, harm encountered and event location.

The sub-menu appears below showing these three main areas:



3.8.2.1 Summary of PINs

Within 'Summary of PINs', the user can specify a time period by month or series of months, or look at the entire collection. The generated report then lists all PINs

contained within reports for this period, and the number of times it appears. A screen capture of the ‘Summary of PINs’ page appears below:

The screenshot displays the 'TAPS PROJECT' application window. The main menu bar includes 'File', 'Edit', 'View', 'Insert', 'Format', 'Records', 'Tools', 'Window', and 'Help'. A toolbar with various icons is located below the menu bar. The central focus is a dialog box titled 'Generate Summary of PINs : Form'. Inside this dialog, the title 'Summary of PINs' is displayed. Below the title, the instruction 'Please select report period:' is followed by three dropdown menus: 'Date' (set to 'Custom'), 'From' (set to '10/2003'), and 'To' (set to '09/2004'). At the bottom right of the dialog, there are two buttons: 'Get Report' and 'Close'. The dialog box also features a record navigation bar at the bottom with the text 'Record: 1 of 1'. The background of the application window shows a logo for 'The Unive Discipline' and a 'Main Menu' button.

3.8.2.2 Crosstab reports

The second subsection within the ‘Summary of report variables menu’ is a section which allows the user to create bi-axial tables, using any of the TAPS questions that participants completed by choosing a discreet variable. The report may be limited to the results of a particular RRMA grouping, or display all RRMA groups combined. A time period may also be specified in months.

The discreet variables from the questionnaire that may be chosen as parameters on either axis include: RRMA grouping (3 options), whether the error related to a patient (2 options), patient sex (2 options), how well do you know the patient (4 options), patient is from a non English speaking background (2 options), patient is of Aboriginal and Torres Strait Islander descent (2 options), where did the error happen (9 options), whether the patient was harmed (2 options), the seriousness of this harm (5 options), how often does this type of error occur (4 options). Answers to questions involving a continuous variable such as age, or questions requiring free text responses, such as ‘what happened?’, are unable to be displayed in this format.

In the following two screen captures for example, the requested table can display the numbers of all reports in the twelve month time period from the RRMA 1 subgroup, with the number of reports in which a patient was harmed along one axis, and the locations of the error events along the other:

TAPS PROJECT

File Edit View Insert Format Records Tools Window Help

Type a question for help

Main Menu : Form

The University of Sydney
Discipline of General Practice

Generate Crosstab Report : Form

Crosstab Report

Please select X Axis and Y Axis to generate your Crosstab Report:

RRAMA Group: 1

X Axis: QK: Where did it happen?

Y Axis: QL: Patient was harmed?

Date: Custom

From: 10/2003 To: 09/2004

Get Report Close

Record: 1 of 1

JAN 20... NUM

TAPS PROJECT - [Crosstab Report QK]

File Edit View Tools Window Help

Type a question for help

Crosstab Report

X Axis: QK: Where did it happen?
Y Axis: QL: Patient was harmed?
Period: From: 10/2003 To: 09/2004
RRAMA: 1

QL	OFFICE	NURSING HOME	HOSPITAL	HOME	PHONE	ER	LAB	PHARMACY	RADIOLOGY	OTHER	Total
Yes	21	5	9	16	3	2	0	1	0	1	58
No	110	12	11	11	3	1	8	11	5	2	174
Total	131	17	20	27	6	3	8	12	5	3	232

Tuesday, 20 February 2007 Page 1 of 1

Page: 1 of 1

Ready NUM

3.8.2.3 Specified queries on age, harm and location

In addition to the bi-axial tables, there were a series of specified queries designed to address some questions around the continuous variable of age, as well as a breakdown of average ratings of harm levels in different event locations, and at different ages. These queries could also be limited by RRMA grouping and time period in months. The example below queries the average age of patients appearing in reports:

The screenshot displays the TAPS PROJECT software interface. The main window is titled 'Specified Queries : Form' and contains the following elements:

- Header:** 'Specified Queries : Age, Harm and Location'
- Instruction:** 'Please select one of these reports:'
- Question Selection:** Three radio buttons are present:
 - AGE Questions
 - Harm Questions
 - Location Questions
- Report:** A dropdown menu is set to 'Average Age of Patients'.
- Detail:** A text box contains the question: 'What is the average age of patients appearing in reports?'
- Date:** A dropdown menu is set to 'Custom'.
- From:** A date dropdown menu is set to '10/2003'.
- To:** A date dropdown menu is set to '09/2004'.
- Buttons:** 'Get Report' and 'Close' buttons are located at the bottom right of the form.
- Footer:** A record navigation bar shows 'Record: 1 of 1'.

The background shows a 'Main Menu : Form' window with the University of Sydney logo and the text 'The University of Sydney Discipline of General Practice'. The top of the screen features a menu bar (File, Edit, View, Insert, Format, Records, Tools, Window, Help) and a toolbar with various icons. The status bar at the bottom indicates 'Form View' and 'NUM'.

Report of Age Questions

What is the average age of patients appearing in reports?

Period From: 10/2003 To: 09/2004

RRAMA Group	Average Age	Number of Patient(s)
1	52.14	180
2-3	49.83	116
4-7	54.24	87
Total	51.92	383

3.8.3 Error coding reports

The third sub-menu of the database management system is entitled ‘error coding reports’ and its options allow various queries to be made of the information that has been entered into a specific error coding page associated with each report.

A major function of the TAPS database management system was to allow the classification of the reports using various different systems. An error coding page was designed that is linked to each individual report. From the displayed error report or set of reports when requested from the ‘view reports’ menu described earlier, there was an option of going into a specific coding page for that report, attached behind it in

the computer programme. The screen capture below shows the coding page for the sample report which appeared previously in the description of the ‘view reports’ area:

The screenshot shows the 'Error Coding Details' window in the TAPS PROJECT software. The window title is 'Error Coding Details'. It contains the following information:

- Summary of TAPS Report no. 148
- Report Description: Incorrect medical management of menorrhagia
- No. of Error Events: 1
- No. of ICPC-2-E RFECs: 0
- ICPC-2-E RFEC: 0
- Error codes: (empty)

Event No	Description	Makeham et al	Linnaeus	ICPCI	Ranking	Comment
1	Incorrect medical management of menorrhagia	2 2 1	0 0 0 0 0 0 0	0 0 0 0		
0		0 0 0	0 0 0 0 0 0 0	0 0 0 0		

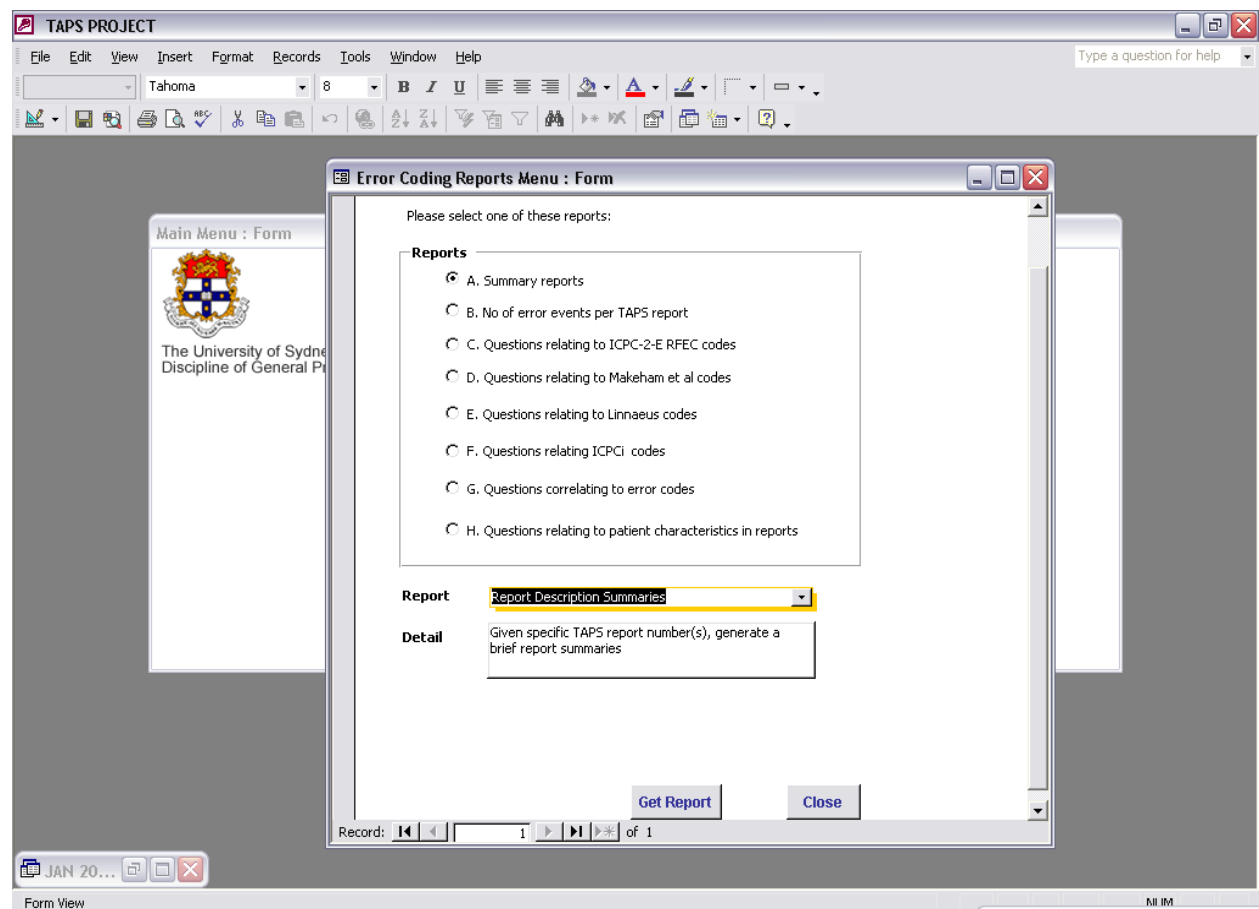
At the bottom of the window, there are buttons for 'Add Event', 'Delete Event', 'Close', 'Previous Record', and 'Next Record'. The status bar at the bottom indicates 'Record: 1 of 1 (Filtered)'.

This error coding page is comprised of information entered by the study investigator coding the reports. The investigator may enter a report description summary, the number of error events that they have seen within the report (to account for cases where a series of separate error events comprise the overall error), and the classification of each of these events using a series of three different classification systems. This thesis addresses the classification system created by using the TAPS reports, later described as the ‘TAPS taxonomy’, and this code was entered in the section on this screen entitled ‘Makeham *et al*’.

The error coding page has been designed with the potential for further classification of the reports by using features of the International Classification of Primary Care (Committee 1998) (ICPC) including ICPC-2 'Reason for Encounter' codes, and a novel ICPC based error classification system, and this work is currently underway but does not form part of this thesis..

There is also the potential for further classification of the reports using a coding system which was created from the international pilot study previously described, the Primary Care International Study of Medical Error (PCISME) (Makeham, Dovey et al. 2002). The code that was created from PCISME has been further developed by researchers at the Robert Graham Center of the American Academy of Family Physicians using subsequently collected reports from several of the original participating countries as well as Germany, and has several hundred descriptors with up to six sub-levels of classifications. It has not yet been published in the peer-reviewed scientific literature, but may be viewed online at www.errorsinmedicine.net/taxonomy/aafp.

The following screen capture shows the error coding reports sub-menu and options:



3.8.3.1 Summary reports

This area has two choices within it, either allowing the user to view the completed report coding page as shown earlier, or to view the report description summaries. The latter of these is the brief sentence or two entered by the coder to describe the contents of the report within the coding page.

In this section, the user can specify that the results be displayed of a single report by entering the report number, of a range of reports by report numbers, or of specified time periods. This options page and a sample of the generated query of report description summaries follows:

TAPS PROJECT

File Edit View Insert Format Records Tools Window Help

Type a question for help

Arial 9 B I U

Error Coding Reports Menu : Form

Please select one of these reports:

Reports

- A. Summary reports
- B. No of error events per TAPS report
- C. Questions relating to ICPC-2-E RFEC codes
- D. Questions relating to Makeham et al codes
- E. Questions relating to Linnaeus codes
- F. Questions relating ICPCi codes
- G. Questions correlating to error codes
- H. Questions relating to patient characteristics in report

Report Report Description Summaries

Detail Given specific TAPS report number(s), generate a brief report summaries

Get Report **Close**

Generate Description Summary : Form

Description Summary

Report Range

- All Reports
- Single Report
- Selected Reports (Please enter report NO#)
- Selected Period

From: 05/2004 To: 06/2004

Get Report **Close**

Record: 1 of 1

Get Report **Close**

Form View NUM

TAPS PROJECT - [qryErrRptA2]

File Edit View Tools Window Help

Type a question for help

100% Close Setup

Report Description Summaries

Record Number	Report Time	Description
305	1/05/2004 9:07:22 PM	Failure of followup high blood glucose/ pathology result, patient presented to ED with hyperglycaemia
306	1/05/2004 9:24:20 PM	Pharmacist dispensed incorrect dose Epilim
307	6/05/2004 7:18:07 AM	Pharmacist incorrectly dispensed Mogaon instead of Maxalon, patient sedated
308	6/05/2004 7:41:40 AM	Misdiagnosis of hypothyroidism by another GP, delayed diagnosis of depression
309	6/05/2004 7:54:09 AM	Delayed diagnosis of mycoplasma pneumonia in child
310	8/05/2004 2:22:43 PM	Perforated tympanic membrane as a result of ear syringing
311	8/05/2004 2:41:28 PM	General thoughts on ethics of investing in companies that return profits influencing choices of patient care
312	11/05/2004 11:04:08 AM	Pathology reports that skin ca excisions narrower incomplete, but on re-excision no residual disease found and patient therefore underwent unnecessary minor surgery
313	11/05/2004 1:29:29 PM	Incorrect dose of morphine given in nursing home
314	11/05/2004 1:49:48 PM	Lab phoned INR to practice; message taking problem at reception resulted in incorrect dose adjustment of warfarin
315	11/05/2004 2:59:55 PM	Patient complaint "GP trawling for business" because GP sent recall letter for BP check, when check was not done at visit in previous week about unrelated matter. GP felt his/her computer recall system being used more effectively could have prevented.
316	11/05/2004 3:09:21 PM	Patient inappropriately treated with antipsychotic medn when actually had

Page: 1 of 1

Ready NUM

3.8.3.2 Number of error events per TAPS report

An entry made by the coder on the error coding page is the number of error events contained within a single report, and the database user in this section can request a list of error report numbers based on the number of events contained within them. This area also allows the user to set parameters of specific time periods in months, or view results of the entire collection.

Within this section, the user may generate the following queries about the collection of report coding pages:

- View a table showing the average number of error events per report by RRMA grouping and overall
- View a table showing raw counts of the number of reports with a specific number of events per report, by RRMA grouping and overall
- View a list of reports that contain a specified number of error events, and from this list be automatically linked to the report details for each listed result via a ‘hot link’ key. (Note also that from this ‘report details’ page the ‘error coding’ page is also immediately accessible using the ‘error coding’ button.)


The following screen captures show a sample of the ‘Number of error events’ sub-menu, with the second option above selected, requesting a table displaying raw counts of the number of error reports with a specific number of error events by RRMA grouping and overall, and the related report:

TAPS PROJECT

File Edit View Insert Format Records Tools Window Help

Type a question for help

Main Menu : Form



The University of Sydney
Discipline of General Practice

Error Coding Reports Menu : Form

Please select one of these reports:

Reports

- A. Summary reports
- B. No of error events per TAPS report
- C. Questions relating to ICPC-2-E RFEC codes
- D. Questions relating to Makeham et al codes
- E. Questions relating to Linnaeus codes
- F. Questions relating ICPCI codes
- G. Questions correlating to error codes
- H. Questions relating to patient characteristics in reports

Report:

Detail: The raw number of error reports per specific number of error events by RRAMA group and overall.

Date:

From: To:

Record: 1 of 1

Form View NUM

TAPS PROJECT - [Report B-2]

File Edit View Tools Window Help

Type a question for help

Average Event Number Report

Period From: 10/2003 To: 09/2004

No events/ report	RRAMA 1	RRAMA 2-3	RRAMA 4-7	Total
0	10	6	2	18
1	150	101	68	319
2	38	17	29	84
3	6	3	1	10
4	1	1		2
Total	205	128	100	433

Page: 1 of 1

Ready NUM

3.8.3.3 Questions relating to Makeham *et al* codes

This sub-menu of the error coding reports menu allows the user to generate reports that relate to the Makeham *et al* code, later referred to as the TAPS taxonomy. This coding method is described in detail in section 3.12, and essentially consists of a three level hierarchical structure, whereby reports are grouped into two main types at the first level. At the second level, type 1 has five subcategories, and type 2 has two subcategories, termed ‘themes’. These themes are then sub-classified again into varying numbers within each group, to give a third level termed ‘descriptors’, of which there are a total of 35 across all seven themes combined.

In this sub-menu, the user has two main options. Firstly, they can generate a list of reports in this section for any given time period in months by specifying a TAPS taxonomy code for which they are searching. They may specify the code at any of the three levels to be included, so that the list could be, for example, all type 1 reports, or reports that are coded as type 1 and theme 2 at the second level, or only those coded as type 1, theme 2 and descriptor 3 at the third level. The generated list has active ‘hot keys’, so that the user can jump straight to the ‘report details’ page from the list, and again from there to the ‘error coding’ page.

The second option available from this sub-menu is to generate a summary report showing all of the TAPS taxonomy codes that have been used in a specified time period, and their frequency of use. As for the former option, the user may specify any combination of code from level one through to level three.

The following two screen captures show the first of these options, moving from the sub-menu through to the requested report of the hyper-linked list of reports using a specific code type. Note also, the list is organised by RRMA sub grouping:

The screenshot displays the 'TAPS PROJECT' application window. The main menu on the left includes the University of Sydney logo and the text 'The University of Sydney Discipline of General Practice'. The 'Error Coding Reports Menu : Form' window is open, showing a list of report options under the heading 'Reports'. The selected option is 'D. Questions relating to Makeham et al codes'. Below the list, the 'Report' dropdown is set to 'TAPS report No list(A specific Makeham et al code)'. The 'Detail' text reads: 'Given a specific Makeham et al code at 1,2 or 3 levels, lists all related TAPS report numbers and total number group by RRAMA.' The 'Date' dropdown is set to 'Custom', and the 'From' and 'To' date fields are set to '10/2003' and '09/2004' respectively. The 'Get Report' and 'Close' buttons are visible at the bottom of the form. The status bar at the bottom indicates 'Record: 1 of 1' and 'NUM'.

TAPS PROJECT

File Edit View Insert Format Records Tools Window Help

Tahoma 8 B I U

Main Menu : Form

The University of Sydney
Discipline of General Practice

Error Coding Reports Menu : Form

Please select one of these reports:

Reports

- A. Summary reports
- B. No of error events per TAPS report
- C. Questions relating to ICPC-2-E RFEC codes
- D. Questions relating to Makeham et al codes
- E. Questions relating to Linnaeus codes
- F. Questions relating ICPCI codes
- G. Questions correlating to error codes
- H. Questions relating to patient characteristics in reports

Report: TAPS report No list(A specific Makeham et al code)

Detail: Given a specific Makeham et al code at 1,2 or 3 levels, lists all related TAPS report numbers and total number group by RRAMA.

Date: Custom

From: 10/2003 **To:** 09/2004

Get Report Close

Record: 1 of 1 NUM

TAPS PROJECT

File Edit View Insert Format Records Tools Window Help

Type a question for help

Arial 9 B I U

Pre Form Report D-1 : Form

Makeham et al codes report

Please input Makeham et al codes:

Level 1

Level 2

Level 3

Record: 1 of 1

Form View

NUM

qryErrRptD1

RRAMA Group	Report Number	
<input type="text" value="1"/>	<input type="text" value="348"/>	<input type="button" value="View Report"/>
<input type="text" value="1"/>	<input type="text" value="377"/>	<input type="button" value="View Report"/>
<input type="text" value="1"/>	<input type="text" value="406"/>	<input type="button" value="View Report"/>
<input type="text" value="1"/>	<input type="text" value="503"/>	<input type="button" value="View Report"/>
<input type="text" value="1"/>	<input type="text" value="507"/>	<input type="button" value="View Report"/>
<input type="text" value="2-3"/>	<input type="text" value="136"/>	<input type="button" value="View Report"/>
<input type="text" value="2-3"/>	<input type="text" value="198"/>	<input type="button" value="View Report"/>
<input type="text" value="2-3"/>	<input type="text" value="214"/>	<input type="button" value="View Report"/>
<input type="text" value="4-7"/>	<input type="text" value="336"/>	<input type="button" value="View Report"/>
Total		<input type="text" value="9"/>

Record: 1 of 9

The next two screen captures relate to the other option within this area, being the request of a report within a given time period showing a list of all TAPS taxonomy codes used and their frequency of use:


TAPS PROJECT

File Edit View Insert Format Records Tools Window Help

Tahoma 8 B I U

Type a question for help

Main Menu : Form



The University of Sydney
Discipline of General Practice

Error Coding Reports Menu : Form

Please select one of these reports:

Reports

- A. Summary reports
- B. No of error events per TAPS report
- C. Questions relating to ICPC-2-E RFEC codes
- D. Questions relating to Makeham et al codes
- E. Questions relating to Linnaeus codes
- F. Questions relating ICPCI codes
- G. Questions correlating to error codes
- H. Questions relating to patient characteristics in reports

Report: Makeham et al code list

Detail: a table showing all Makeham et al codes used and their frequency of use

Date: Custom

From: 10/2003 **To:** 09/2004

Get Report Close

Record: 1 of 1

JAN 20... Form View NUM

TAPS PROJECT - [Report D-2]

File Edit View Tools Window Help

Fit Close Setup

Type a question for help

Makeham et al Code List

Period From: 10/2003 To: 09/2004

Makeham et al Code	No of events using this code
1 . 1 . 1	12
1 . 1 . 2	13
1 . 1 . 3	28
1 . 1 . 4	23
1 . 1 . 5	6
1 . 1 . 6	6
1 . 1 . 7	6
1 . 1 . 8	5
1 . 1 . 9	8
1 . 2 . 1	7
1 . 2 . 2	12
1 . 2 . 3	9
1 . 2 . 4	33
1 . 2 . 5	2
1 . 3 . 1	31
1 . 3 . 2	16

Thursday, 22 February 2007 Page 1 of 5

Page: 1 of 1 Ready NUM

3.8.3.4 Questions relating to patient characteristics within reports

This area allows the database user to generate queries that link coded TAPS reports with a range of different patient characteristics as entered by the TAPS participants when submitting error reports. The system is designed for three coding styles as previously described being the TAPS taxonomy, the Linnaeus taxonomy, and a novel ICPC based error taxonomy. For the purposes of this thesis, only TAPS taxonomy methods and results are described.

There are four main options within this section, as follows:

- Given a specific code, generate a table showing proportions of male and female patients affected by RRMA group and overall
- Given a specific code, generate a table showing the average age of patients affected by RRMA group and overall
- Given a specific code, generate a table showing the distribution of the nine locations of the error event by RRMA group and overall
- Given a specific code, generate a table showing the proportion of whether or not harm occurred and the average harm rating by RRMA group and overall

An example of this is shown in the following screen captures, where reports coded as type 2 and theme 2 are queried for the number of patients involved where harm was reported to have occurred, by RRMA grouping and overall:

TAPS PROJECT

File Edit View Insert Format Records Tools Window Help

Type a question for help

Error Coding Reports Menu : Form

Error Coding Reports Menu

Please select one of these reports:

Reports

- A. Summary reports
- B. No of error events per TAPS report
- C. Questions relating to ICPC-2-E RFECC codes
- D. Questions relating to Makeham et al codes
- E. Questions relating to Linnaeus codes
- F. Questions relating ICPCI codes
- G. Questions correlating to error codes
- H. Questions relating to patient characteristics in reports

Report: Proportion of harm occurred

Detail: Given a specific code, generate a table showing the proportion of whether or not harm occurred and the average harm rating by RRAMA group and overall.

Date: Custom

From: 10/2003 **To:** 09/2004

Pre Form Report H-4 : Form

Proportion of harm occurred

Please select one type of error codes and input a code:

Error Code Type

Makeham et al Linnaeus ICPCI

Level 1: 2

Level 2: 2

Level 3: ALL

Record: 1 of 1

Buttons: Proportion of harm, Avg harm rating, Close

TAPS PROJECT - [Report H-4]

File Edit View Tools Window Help

Type a question for help

Proportion of harm occurred

Makeham et al Level 1: 2
 Makeham et al Level 2: 2
 Makeham et al Level 3: ALL

Period From: 10/2003 To: 09/2004

RRAMA Group	Number of Patient(s) (HARM)	Number of Patient(s) (NOT HARM)	Total
1	15	29	44
2-3	11	17	28
4-7	13	10	23
Total	39	56	95

Page: 1 of 1

Ready

3.8.3.5 Other functions within the error coding reports menu

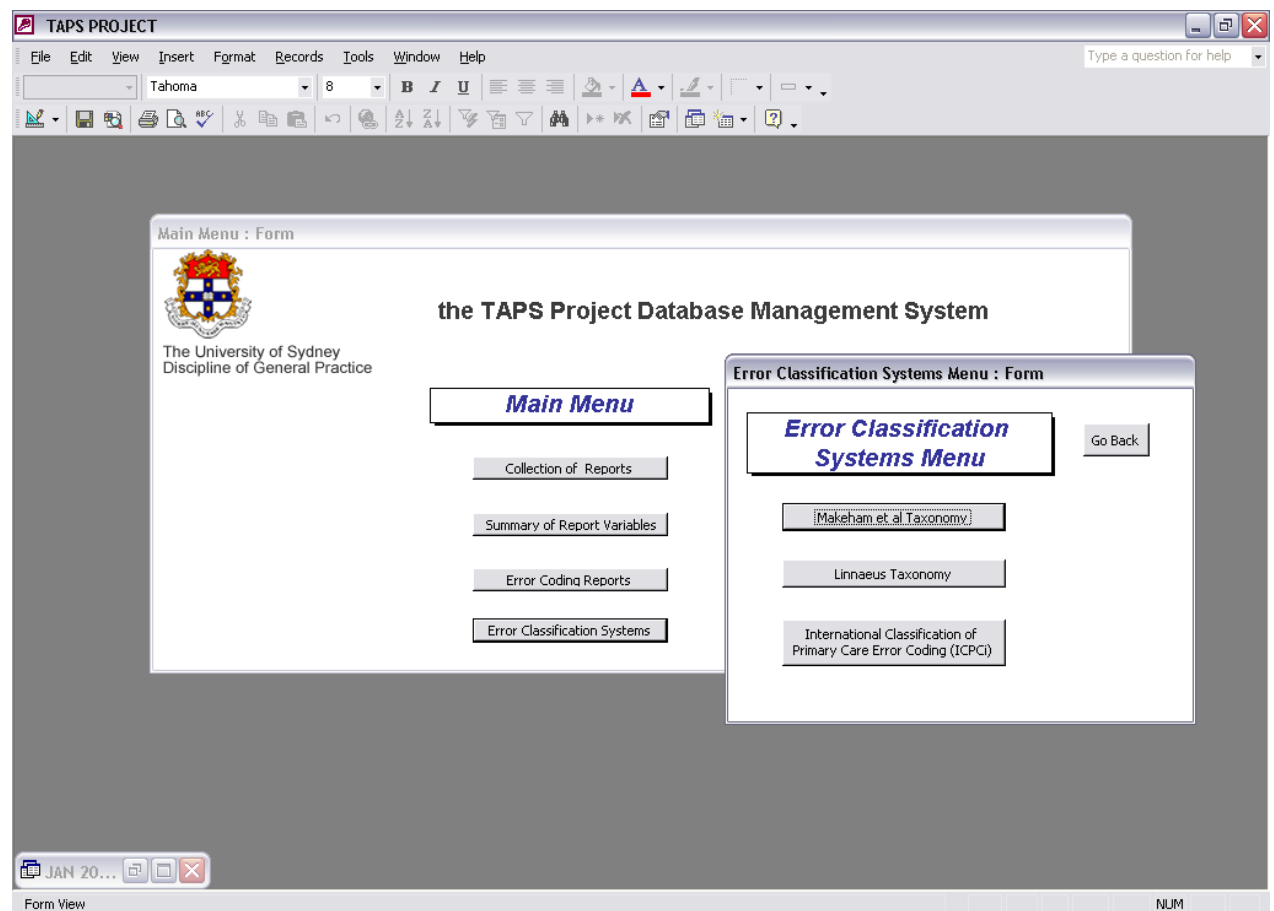
Also present on the 'error coding reports' menu are four further sections. They will not be discussed in detail as they contain a number of queries relating to work developing future tools which is underway and not directly relating to the TAPS taxonomy or the objectives of this thesis:

- ICPC 'Reason for encounter' codes
- Linnaeus taxonomy codes
- The ICPC based error coding system under development and
- Correlation between the three potential coding systems built into the database, being TAPS, Linnaeus and the ICPC based error coding system

This latter section will allow, for example, a list of all the codes from the Linnaeus taxonomy and the ICPC based error taxonomy that have been used when a given TAPS taxonomy code was used at any of the first, second or third levels of the code. Similarly, a code from one of the other systems can be used as the base code in the query, and the lists of the other two code types can be displayed.

3.8.4 Error classification systems

This is the final of the four Main menu options, and is designed to allow the user to view the three taxonomies built into the database. The screen capture of the sub-menu appears below, and the user is taken to a description of each coding system by selecting the appropriate taxonomy button:



3.9 Sampling from the population of GPs in NSW

3.9.1 Definition of general practitioner

For the purposes of inclusion in the random sample to be generated by the General Practice Branch of the Commonwealth Department of Health and Aging (DOHA), a general practitioner was included based on the following criteria:

- Medical practitioner having a general practice provider number in the state of NSW.
- Working a full-time load in the three months prior to the sample being drawn as defined by DOHA based on annual Medicare billings of greater than or

equal to \$83,000. This was calculated for the October to December quarter of 2002, which directly preceded the actual sampling in February of 2003.

- Being on the general practice vocational register for the purposes of Medicare claims, which requires satisfaction of continuing education requirements.
- Not being a general practice registrar or “Other Medical Provider” as determined by DOHA.

3.9.2 Definition of source population

Further references in this thesis to the ‘source population’ is the group of NSW general practitioners meeting the definition above, based on DOHA data for the October to December quarter of 2002, numbering 4666 general practitioners in total.

3.9.3 Sample size

Sample size calculations were undertaken in order to estimate the incidence of reported error per consultation per year. A required sample size of 80 was calculated from the Primary Care International Study of Medical Error (PCISME) pilot study results from Australian participants of 134 reports made from up to 23 GPs over four months (Makeham, Dovey et al. 2002). Allowing one week of absence each and estimating an average of 132 consultations per week, being the figure estimated by a major DOHA publication on general practice in Australia in 2000 (General Practice Branch 2000), we hypothesized a reported error rate of 0.27% per consultation. An estimation of this would be allowed based upon 205,465 patient encounters with a 95% confidence interval from 0.25 to 0.29%. We anticipated that 80 participants

would conduct approximately 480,000 consultations, with the excess allowing for any effect of clustered samples.

The General Practice Branch of the Commonwealth Department of Health and Aging (General Practice Branch) drew a random sample of 320 names from the source population of vocationally registered general practitioners in NSW whose Medicare billings in the previous quarter indicated that they were working in a full-time capacity. This figure was chosen to allow for a similar participation rate to the pilot study, of approximately 25% (Makeham, Dovey et al. 2002).

It is difficult to assess whether or not a figure of 25% was a reasonable response rate to obtain in a study such as TAPS. There were no other studies of this kind found in the literature that used a random sampling method. Other similar error studies had obtained their participants essentially by volunteer (Britt, Miller et al. 1997; Bhasale 1998; Bhasale, Miller et al. 1998; Makeham, Dovey et al. 2002). In order to assess that the response rate was adequate in terms of providing a representative sample of GPs, the participant group was compared in terms of age, gender and Medicare billing characteristics to the source population, and these results are presented in section 4.3, showing that the sampling method and response rate were successful in these respects.

3.9.3.1 Cluster effect on sample size calculations

The cluster effect is generally found from having groups of results of varying numbers contributed by single participants, as we had with our 84 GPs sending various numbers of reports. The result of this is largely to reduce the power of our calculations. As we believed that clustering would exist using the methodology

employed, we doubled our sample size, in order that we could maintain power after adjusting for clustering in the appropriate analyses. Another way of explaining this is to say that we sampled 320 GPs in order to obtain 80 participants, which would provide the 480,000 consultations, although only 205,465 were required if no clustering was anticipated.

3.9.4 Rural, Remote and Metropolitan Area (RRMA) distribution

The sample was drawn from three Rural, Remote and Metropolitan Areas (RRMA) groupings of RRMA 1, RRMA 2-3, and RRMA 4-7 (Budget and Performance Branch 2005). The sample was comprised of 50% (160) from RRMA 1, 25% (80) from RRMA 2-3 and 25% (80) from RRMA 4-7 regions. This compared to DOHA figures for full time GPs in NSW of 68%, 16% and 16% within these groupings in the source population respectively. The smaller subgroups were over-sampled to ensure adequate counts of Medicare items to allow future subgroup analysis.

3.9.5 Age and gender distribution

The General Practice Branch provided a sample stratified by gender and age, dichotomized around 45 years, to best reflect the source population. This stratification was undertaken within the three main Rural, Remote and Metropolitan Areas (RRMA) groupings of RRMA 1, RRMA 2 to 3 combined and RRMA 4 to 7 combined. Age was taken as that of the participant at the mid-point of the data collection period, being 31st March 2004.

3.10 Recruitment and consent process

All general practitioners from the random sample were invited to participate by telephone call. If interest was expressed, an information pack was sent. These doctors were then contacted by follow-up telephone call. Reasons were recorded for absence of a doctor from the sample, or declining to participate in the study. All general practitioners who commenced the study were visited in person at their practices across NSW to obtain informed consent and demonstrate the electronic error reporting method using a laptop computer.

3.10.1 General inclusion criteria for participation

General practitioners who were contacted from the random sample were deemed eligible to participate in the TAPS study if they met the criteria shown below in figure 3.2, in addition to those requirements for inclusion in the initial sample by the General Practice Branch:

Figure 3.2 Eligibility criteria for participation in the TAPS study.

1. Practicing in general practice.
2. Usually provides direct patient care for the majority of their work time (at least 20 hours per week).
3. Usually will be absent from their clinical work setting for no more than six weeks out of the twelve months data collection period of the study.
4. Comfortable with use of computers and have access to a personal computer (pc)
5. Able to establish reliable internet access via an internet service provider (ISP).
6. Willing to participate in the study.

3.10.2 Participant's Medicare data collection

Consent was also obtained for the collection of each participant's Medicare billing data, for all services provided over the same 12 month duration as the reporting period. Details of each practitioner's item number counts and numbers of whole patients seen were calculated by the General Practice Branch, and provided quarterly. The calculation of the numbers of Medicare items and patients seen per GP was delayed for three months from the end of each quarter during the study. This was to allow greater accuracy with service counts than a determination on the final day of a quarter would provide, at which time variable numbers of claims to Medicare may not yet have been lodged by patients or practices.

Participants were informed that only de-identified aggregated Medicare data would be used for calculations in the study, pooled according to RRMA classification prior to analysis. There were no records kept linking an individual GP to his or her Medicare data, and no analysis or publications of an individual doctor's Medicare data set. Because there was no way of linking an individual participant's Medicare data with their group of anonymously submitted reports, there was no possibility of determining an individual participant's reported error rate or any other details of error types reported by an individual participant.

3.10.3 Participant background information

At the time of enrolment, the data shown in figure 3.3 below was collected from each participant identified by RRMA grouping to determine some basic demographic and

practice characteristics of the participant group. The full text background questionnaire is included as Appendix 3.

Figure 3.3 Participant demographic and practice data collected at enrolment.

- | |
|--|
| <ul style="list-style-type: none"> • Age in years • Years in practice (excluding training) • Gender • Number of half-days worked in clinical practice in a usual week • Number of patients seen on a usual half-day of clinical work • Whether medical students, residents, or registrars are taught in the practice • Number and full-time equivalent number of doctors practicing in the practice • Number and full-time equivalent number of other people working in the practice • Use of computers in the practice |
|--|

3.10.4 Comparison of TAPS participants to NSW general practitioners

The total number of general practitioners (GPs), the proportions of male and female GPs, and average age of GPs at the mid-point of the study were obtained by RRMA groupings, for both the 84 study participants and the source population of 4666 NSW general practitioners from which the sample was drawn. The General Practice Branch also provided the number of Medicare items billed that related to a patient encounter over the twelve months of the study for these two groups.

This enabled a comparison of the study participants overall and by RRMA groupings with all NSW GPs. The percentage of female GP participants was compared to the source population using Fisher's Exact Test. The average age and number of

Medicare items relating to patient encounters for these groups were compared using unpaired student t-tests.

3.10.5 Participant support and feedback

As discussed earlier, the TAPS website features enabled contact to be made in three main ways, being from the security page if passwords or pins were forgotten, from the home page in 'contact the investigators', or in the 'other comments' feed back at the end of a report.

In addition to these features, every participant was contacted monthly by email, telephone call or facsimile and asked whether any other errors had been noted that they may have been too busy to report on-line in the previous month, or whether they had experienced any problems with the website.

Furthermore, all participants were given TAPS packages with written information at their enrolment which contained the mobile phone numbers of the Chief Investigator (Meredith Makeham) and the Project Manager (Geraldine Card), and invited to call at any time immediate support was required. The project policy was to endeavour to respond to any requests for support within 24 hours of contact from a participant.

Another support feature of the TAPS project was that each participant was offered an entitlement to claim a small one off honorarium of \$200, which was intended to offset any internet connection and phone call costs that would be incurred as part of their participation in the TAPS study.

3.11 Quantifying the number of errors reported

3.11.1 The overall number of reported errors

The overall number of reports submitted per participant was not possible to calculate directly due to the measures taken to ensure anonymity. The best approximation that could be made of this was therefore the number of reports submitted per PIN, which was not necessarily the same as there was no way of being certain that an individual participant had not changed their PIN at any point over the twelve months of the study. The number of errors reported per PIN, the number of PINs obtained per RRMA group, and the total numbers of errors from the group was obtained from the website data.

A feedback interview at the conclusion of the study checked whether participants believed that they had sent any reports electronically. The feedback interview provided another source of the number of participants who submitted at least one report during the twelve months of the study. To protect anonymity and investigator blinding, we did not ask individual participants the number of reports submitted.

Calculations were therefore made of both the number of reports per PIN, and the number of reports per participant. These rates were able to be calculated for the overall group and by RRMA grouping.

3.11.2 Calculating the incidence of reported error

An incidence calculation essentially requires three elements: a *numerator*, in this case being the number of reports received from the TAPS participants; a *denominator*,

being either the number of individual patients seen by the participants, or the number of consultations they gave, which is considerably greater due to the fact that the same patient may attend a general practitioner on several occasions within a set time period for unrelated consultations; and a *time period*, in this study being the twelve months for which data was collected.

The numerator was calculated by simply counting the total number of reports submitted using the website data. The denominator was obtained in both possible ways described above. Firstly, counts of the number of Medicare items billed that related to a patient encounter over the twelve months of the study were used to calculate the incidence of anonymously reported error from NSW general practitioners per patient encounter Medicare item per year. Secondly, the number of individual patients that were seen by the participant group over the study time frame was used to calculate the incidence of reported error from NSW general practitioners per patient seen per year.

Patients who were seen on more than one occasion during the year by a single participant were only counted once per general practitioner. If a patient saw more than one TAPS participating general practitioner during the study period, they were counted again in the overall figure, to best reflect an average number of individuals seen per year by each participating general practitioner.

Our initial sample size calculations aimed to provide sufficient power to estimate these incidences for the population of NSW general practitioners, and this required the entire participant group's data set. A calculation of incidence within the smaller

RRMA sub-groupings was therefore not made, as a greater number of participants per grouping would have been required, which was not practicable within the resources available to conduct the study.

3.11.3 *Data Analysis of numbers of reports per PIN and incidence calculations*

A non-parametric method with Fisher's Exact Test was used to compare the median number of reports per PIN. Incidence calculations included sampling weights for the three RRMA groupings to adjust for the relative over-sampling of RRMA 2-3 and 4-7 GPs. All statistics were performed using Stata 8.0 software (Stata Corporation 1984 - 2003).

3.12 *Classifying the errors contained in TAPS reports*

3.12.1 *Overview*

The Threats to Australian Patient Safety (TAPS) study estimated the incidence of general practitioner (GP) reported patient safety events in the community, using a method based upon a randomly selected representative sample of GPs (Makeham, Kidd et al. 2006). With this collection of reports, it was therefore possible to postulate more accurately the proportions of reported patient safety event types occurring in the community. This required the application of a classification system, however major limitations (mainly relating to the internal validity of existing tools) warranted further taxonomy development.

To describe the TAPS events, the aim was to develop a taxonomy that would be comprehensible and practical for primary care clinicians to apply themselves. This section of the thesis describes the methods for that process, in addition to the methods to validate a primary care taxonomy in terms of its reproducibility within a group of general practitioners applying the tool.

3.12.2 TAPS Taxonomy development methods

3.12.2.1 PCISME pilot taxonomy

Three GPs from the investigating team (Meredith Makeham, Simone Stromer and Charles Bridges-Webb) classified each report using the existing pilot study taxonomy from the Primary Care International Study of Medical Error (PCISME taxonomy)(Makeham, Dovey et al. 2002), and the results were compared to obtain a baseline measure of reproducibility.

The basic structure of this taxonomy is a three level classification using descriptive terms, whereby the top level separates events into two main types, being errors related to the processes of delivering health care ('process'), or errors related to a deficiency in the knowledge and skills of health care professionals ('knowledge and skills'). At the second level, there are six further terms describing 'process' errors, and three further terms describing 'knowledge and skills' errors. These second level terms then have a third further level of descriptions with varying numbers of terms within each second level group, made up of 24 in the 'process' group and 11 in the 'knowledge and skills' group, totalling 35 in all at the third level. This taxonomy was published in 2002, and appears as Appendix 4.

3.12.2.2 Team coding process

A systematic process of reviewing disagreeing classifications was carried out, whereby the initial taxonomy was amended and retested using one quarter of the reports each time, over four face to face sessions. A report required two out of three reviewers in agreement to be assigned a classification.

Reports containing more than one event were given multiple classifications. If it was determined that multiple events had occurred within a report, these codes were assigned in chronological order, as they appeared in the free text of the report.

Where three different classifications had been assigned by the three reviewers, the report was reviewed at a face to face meeting to determine its classification. A discussion then ensued within the group with each reviewer explaining their reasons for coding, and a resolution was reached when two of three came to an agreed classification or set of classifications for each discussed report.

A set of guidelines to improve coder consistency when using the taxonomy was also developed during these meetings.

3.12.2.3 Agreement of investigators developing the taxonomy

Concordance amongst the coders was measured using the kappa statistic, for both the initial taxonomy and the final TAPS taxonomy. To determine this statistic, the results of each reviewer prior to discussion as per the team coding process were used.

Only one classification per report was included for the kappa score calculations. If reports were assigned multiple classifications by one or more coders, the first classification most commonly assigned was included.

The kappa statistic can range from -1 (perfect disagreement) to +1 (perfect agreement). A kappa score of between 0.40 and 0.75 indicates fair agreement. (Fleiss 1981; Bolton, Mira et al. 1997) All statistical analysis was performed using Stata 8.0 software. (Stata Corporation 1984 - 2003)

3.13 The TAPS taxonomy proportions of reported error types

The classification of the error reports using the TAPS taxonomy provided a measure by which the relative proportions of different reported error types could be determined. These proportions are presented for all events contained within the reported errors.

The TAPS taxonomy is presented with an analysis of its major variations from the pilot taxonomy, and a discussion the types of errors included within each level 2 or 'theme' grouping. Case studies of the major error types and themes are presented to further illustrate the TAPS taxonomy.

3.14 Patient related factors in reported errors

An analysis of the patient factors which were reported by participants in the TAPS questionnaire about each error was undertaken. These include whether or not a patient was involved in a reported error, how well the GP participant knew the patient

on a 5 point rating scale, the average patient ages as well as proportions relating to gender, Non-English Speaking Background (NESB) and Aboriginal and Torres Strait Islander (ATSI) peoples.

A further analysis of these factors was undertaken, considering associations with the main types of errors reported, as classified using the TAPS taxonomy, to identify if there were any particular trends with patient factors and error event types.

3.15 Event locations of reported errors

GP participants were asked in the questionnaire to indicate where the error occurred, choosing from a set of nine locations. The proportion of events occurring in each location was determined. Participants were able to indicate more than one location associated with a report if desired, and the proportion of reports from each location associated with any of the other locations was also undertaken to identify any association trends. In addition, location of error report by error event type as classified using the TAPS taxonomy was made to see if any particular trends emerged with types of events and their location of occurrence.

3.16 TAPS reports associated with patient harm

In addition to analysing the reported harm level associated with the commonly reported error types, an analysis of all reports which were associated with patient harm was undertaken.

As part of the TAPS questionnaire, participants were asked “To your knowledge, was any patient harmed by this error?”. If they answered in the affirmative, they were then shown the question “How would you rate the seriousness of this harm?”, and given a 5 point Likert scale to click a number on from 1 to 5, with a label before the number 1 being “Not serious at all”, and after the number 5 being “Extremely serious”. No clear definition of “patient harm” or the term “serious” was given within the questionnaire, and some differences of interpretation were likely to have occurred.

An analysis of harm was then undertaken by determining the proportion of reports and events in which harm had been determined positive by the participants. The proportion of harm positive reported errors was calculated and they were then analysed in terms of their error type based on TAPS taxonomy classification and their association with patient demographics (age, gender, ATSI and NESB).

A standard chi-squared test of overall association was conducted, whereby frequencies of type of error and harm, and number of errors and harm were summarised using cross-tabulations. The associations between type of error and harm, and number of errors and harm were assessed using a chi-squared test.

3.17 Preventability of reported errors

Participants were asked to identify any factors that may have prevented this or any other similar error events, and commented on this with a free text response. If none were offered, further consideration of the report by the Chief Investigator (MM) was undertaken with respect to preventability. The proportion of reports in which a

prevention idea was offered, both by participants or the Chief Investigator, was measured.

3.18 Reported error types considered to occur frequently in general practice

The questionnaire also asked participants to indicate within four main groups how frequently they felt that the type of error that they had just reported occurred in their daily practice. The distribution of the 'frequency of occurrence' score for each error type as classified by the TAPS taxonomy at the second taxonomic level is presented in a bar chart format.

3.19 Participant feedback interview

At the conclusion of the twelve month study, each participant was contacted for a feedback interview. These were conducted by telephone by the TAPS Project Manager (Geraldine Card). The interview covered four main areas, being participation habits, time requirements, error interpretation and severity of harm associated with given error scenarios.

For the purposes of data analysis relating to the objects of this thesis, the following feedback questions are included in the results of this thesis, and they pertain to questions of the practical use aspects of a system such as TAPS. These were the questions of whether the online reporting system was easy to use for GPs, how long it took to submit reports, and whether anonymity impacted on reporting habits.

The telephone script for these questions was as follows:

1. Did you submit any on-line reports during the study?
2. How would you rate the ease of use of the TAPS website from 1 to 5, where 1 is “easy” and 5 is “difficult”
3. If error reporting was not anonymous, would you be more likely or less likely to place a report?
4. About how many minutes did it take you to send an on-line error report?

4 Results

4.1 Overview

This section of the thesis describes the results obtained in the TAPS study that relate to the principle aims set out in section 1.3. The results of participant sampling and recruitment are presented, with a comparison of the participant group to the source population from which they were sampled.

The results relating to various aspects of quantifying TAPS error reporting are given, including total numbers of reports received by month, total numbers of personal identification numbers (PINs) used by participants, the average numbers of reports per PIN, and the incidence of reported error per patient seen and per Medicare item number claimed. These results have all been published in the peer-reviewed scientific literature (Makeham, Kidd et al. 2006), shown in Appendix 6.

The contents of the error reports are then presented, classified using the TAPS taxonomy. This taxonomy, the agreement of the coders and the proportions of error types in the TAPS data using this taxonomy has also been published in the peer-reviewed scientific literature (Makeham, Stromer et al. 2007), shown in Appendix 7.

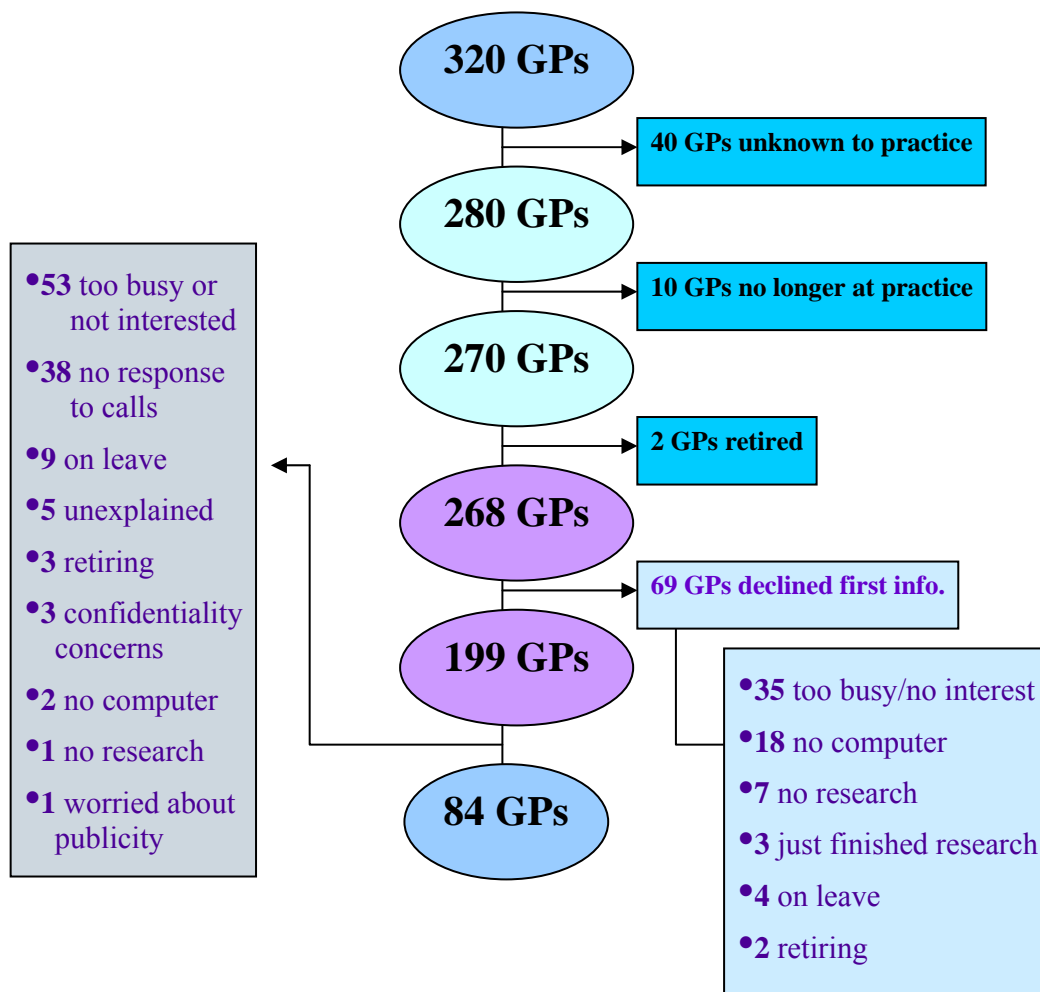
Features of the group of reported errors overall are described, including patient demographics, event locations, associated levels of patient harm, preventability of reported errors and participant's impressions of the frequency of reported error types. An analysis of these features is also presented as relates to the reported events as classified using the TAPS taxonomy to the second taxonomic level.

The final set of results in this section relate to the relevant sections of the feedback questionnaire, relating to ease of use of the TAPS website, the number of minutes to complete a questionnaire, and the proportion of participants who felt that anonymity influenced the likelihood that a report was submitted.

4.2 Numbers of participants in the TAPS study

The General Practice Branch of the Commonwealth Department of Health and Aging provided a random sample of 320 general practitioners (GPs), as described previously in section 3.9. From the sample of 320 doctors provided by the General Practice Branch, we were unable to locate 52 general practitioners (16%) who had either moved away, retired, or were completely unknown to the practice. Of the remaining 268 doctors, 69 declined the first information pack, the majority stating that they were too busy or not interested, and 18 declining because they had no computer. Of the 199 GPs who received the information pack, 115 later declined after further contact, resulting in 84 GP participants at the commencement of the study. Figure 4.1 presents a flow diagram of the original sample and resulting 84 participants.

Figure 4.1 Flow diagram of General Practice Branch sample and resulting study participants



The 84 GP participants enrolled at the commencement of the study were comprised of 41 RRMA 1, 22 RRMA 2-3 and 21 RRMA 4-7 GPs. During the reporting period, one participant from RRMA 1 and one from RRMA 4-7 left the study. Their results were included in our further calculations unless otherwise stated, as anonymous reporting resulted in it not being possible to ascertain if they had contributed any reports up until the point of leaving.

4.3 Comparison of the TAPS participants to the source population

The total number of GPs, their sex and average age were obtained from the General Practice Branch by RRMA groupings at the time the random sample was generated, enabling comparison of the study participants to the source population of the 4666 NSW GPs from which the sample was drawn. The number of Medicare items billed that related to a patient encounter over the twelve months of the study for these two groups was also provided by the General Practice Branch for comparison. There was no significant difference between the participants and source population, within each RRMA sub-grouping or for all combined, using any of these measures.

4.3.1 TAPS participant gender distribution compared to NSW GPs

Table 4.1 shows the percentage of female general practitioners in the TAPS participant group compared to the underlying percentages in the source population from which the sample was drawn, using figures provided by the General Practice Branch of the Department of Health and Aging at the time that the random sample was generated. Using Fisher's exact test, for all RRMA groupings combined and within each RRMA sub-grouping, there was no significant difference found.

Table 4.1 The percentage of female general practitioners in the participant group compared to the source population.

	RRMA 1 % female	RRMA 2-3 % female	RRMA 4-7 % female	All doctors combined % female
TAPS participants (n = 84)	22.0%	9.5%	22.7%	19.0%
Source population (n = 4666)	29.8%	24.2%	17.9%	27.0%
Fisher's exact p value	0.3065	0.1278	0.5721	0.1071

4.3.2 TAPS participant average age compared to NSW GPs

The average age of GP participants in comparison to the source population of 4666 NSW GPs using the Student's t-test is shown in table 4.2, showing no significant difference between TAPS participants and the source population at the 5% significance level.

Table 4.2 The average age of TAPS participants in comparison to NSW GPs.

	RRMA 1 Average age (SD)	RRMA 2-3 Average age (SD)	RRMA 4-7 Average age (SD)	All combined Average Age (SD)
TAPS participants (n = 84)	51.7 (8.70)	50.8 (8.48)	49.5 (9.10)	50.9 (8.69)
Source population (n = 4666)	52.4 (10.56)	52.2 (10.11)	51.2 (10.11)	52.2 (10.43)
Two-tailed P value	0.6740	0.5267	0.4281	0.2680

4.3.3 The number of Medicare Items billed by TAPS participants compared to NSW GPs

Over the twelve months of the study, the General Practice Branch counted the number of Medicare Item numbers claimed by each GP participant that could have related to a patient encounter. This was the closest approximation that could be made to a unique patient consultation using Medicare data. The same figures were also calculated by the General Practice Branch for the source population of 4666 GPs from which the sample was drawn. The average number of patient encounter Medicare Items and their standard deviations for participants and the source population are compared using the Student's t-test in table 4.3, showing no significant difference.

Table 4.3 The average number of patient encounter Medicare Items per general practitioner over the study period in the participant group compared to the source population of 4666 NSW general practitioners.

	Average Number of patient encounter Medicare Items (SD)			
	RRMA 1	RRMA 2-3	RRMA 4-7	All combined
TAPS participants	5782.79 (3839.17)	5247.86 (2880.68)	4808.81 (1565.59)	5389.84 (3136.67)
Source population	5917.12 (3517.51)	5667.03 (3264.16)	4605.93 (2503.22)	5671.58 (3370.13)
P value	0.8129	0.5521	0.7122	0.4527

4.4 The number of TAPS reports submitted

During the 12 months of the study, 433 report forms were sent using the TAPS website, 15 of which contained no information or a test message. The 418 remaining TAPS reports described an error, identified only by the participant's self-chosen personal identification number (PIN) and RRMA grouping.

Initial analyses were done with and without adjustment for clustering in the sample, but it was found that the design effect was very close to one, and therefore analyses were conducted without adjustment for clustering for the sake of simplicity in the thesis.

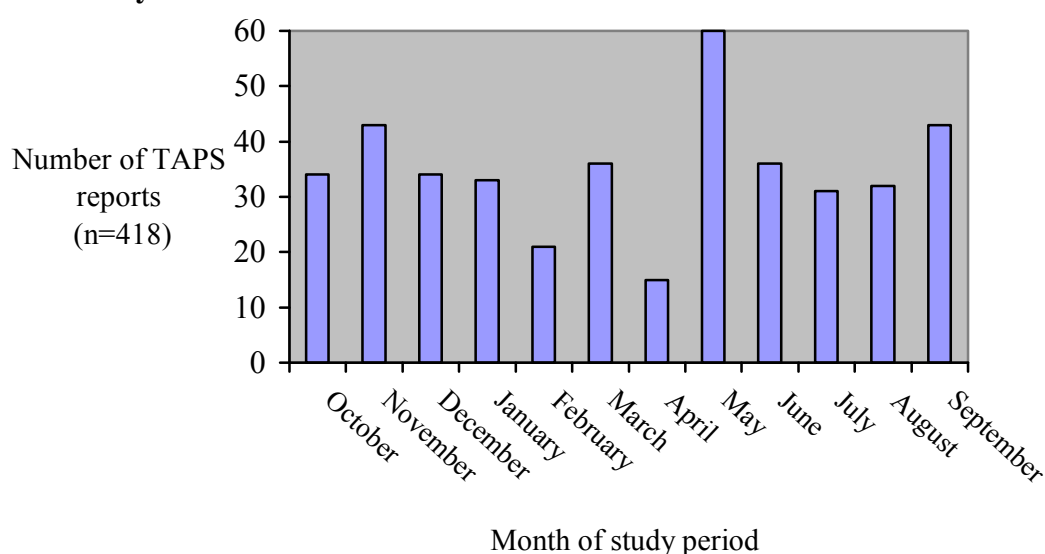
4.4.1 Personal identification numbers submitted during the study period

For the purposes of further calculations, a PIN was combined with another on twelve occasions where they differed only by capitalization, or appeared highly similar with a difference in either one or two of the eight possible characters. (For example "271260" was combined with "27121960"). This resulted in 90 unique PINs. Five of these PINs were associated with a test report having been sent, but no further completed TAPS reports. Therefore the 418 TAPS reports originated from 85 unique PINs. At 12 month feedback interview with the 82 participants who completed the study, 79 fed back that they had submitted a report.

4.4.2 TAPS reports submitted per month during the study period

Figure 4.2 shows the number of reports received per month, which varied from 15 to 60. The overall appearance of this chart indicates that there was no general decline in reporting as the twelve month study period progressed.

Figure 4.2 The number of TAPS reports received by month over the duration of the study.



4.4.3 TAPS reports submitted per PIN and per GP participant

There was no way of equating PINs with individual participants, and so the twelve month feedback interview was used to assess how often more than one PIN may have been used by participants. Table 4.4 shows RRMA grouping comparisons of the number of TAPS reports submitted, PINs submitted, GPs who fed back that a report was sent during the study, average number of reports per GP based on feedback, and the median number of reports per PIN over the duration of the study.

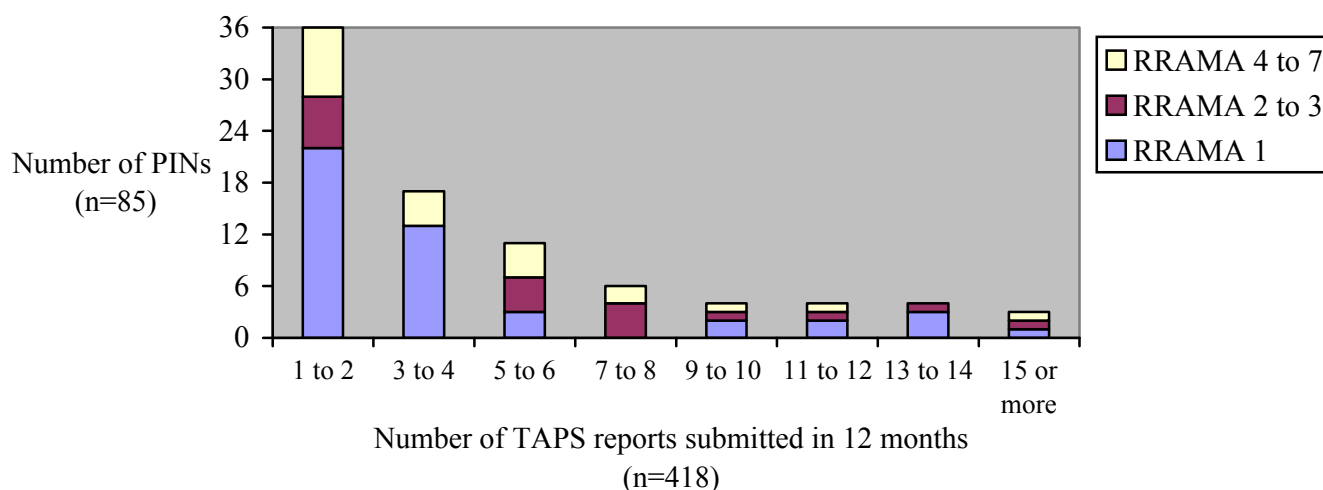
Table 4.4 Summary statistics describing TAPS reports submitted by RRMA group over the study period.

RRMA Group	Number of participants	TAPS Reports received	Unique PINs submitted	GP sent a report	Average reports per GP	Median number of reports per unique PIN
1	41	199	46	38	5.2	3
2-3	22	121	18	21	5.8	6
4-7	21	98	21	20	4.9	4
Total	84	418	85	79	5.3	3

4.5 Frequency of error reporting amongst RRMA groupings

The distribution of reporting frequencies amongst RRMA groupings was assessed by looking at the number of reports per PIN. This varied from 1 to 25, with a median of 3 reports per unique PIN for all participants combined. Figure 4.3 shows the frequency of reports submitted per PIN, separated into RRMA groupings. There was no significant difference amongst RRMA groupings in the median number of reports submitted per PIN, splitting values equivalent to the median equally between the above and below group ($p = 0.40$).

Figure 4.3 Frequency of reporting per unique PIN by RRMA grouping over 12 months.



4.6 Incidence of reported error

The total numbers of Medicare items relating to a patient encounter and total numbers of individual patients seen by RRMA grouping are shown in table 4.5. Each report within a RRMA grouping was matched with the group's average number of Medicare items and average number of patients seen, and assigned a sampling weight to adjust for the larger representation of RRMA 2-3 and 4-7 GPs in the sample design.

The resulting calculations gave an incidence of anonymously reported error per Medicare patient encounter item per year of 0.078% (95% CI 0.076% to 0.080%), and an incidence of reported error per patient seen per year of 0.240% (95% CI 0.235% to 0.245%).

Table 4.5 The number of Medicare items relating to a patient encounter and individual patients seen by TAPS participants during the study.

	RRMA 1	RRMA 2-3	RRMA 4-7	All RRMA
Medicare Items	260150	127610	103104	490864
Patients seen	89042	45176	32351	166569

4.7 TAPS Report description summaries

The TAPS database management system allowed the investigators to view a completed report and enter a brief summary of its contents into its coding area, as described previously in section 3.8.3. These 'description summaries' provide a general overview of the contents of each of the submitted TAPS reports during the study period, and are included in this thesis as Appendix 5.

4.8 Number of error events per TAPS report

As detailed in the methods section 3.12 of this thesis, the collection of TAPS reports was analysed by three general practitioners on the study team (Dr Meredith Makeham, Dr Simone Stromer and Prof Charles Bridges-Webb AO). As the first step in the process of classifying a report, it was necessary to determine if in fact it contained an error as per the definition described to study participants.

It was also possible for a TAPS report to contain more than one patient safety event within the report, and when two or more investigators agreed that a separate event had occurred and assigned it a classification, it was counted within the report's 'number of error events'.

Altogether 433 website submissions were received, with 415 containing true reports after discounting tests and reports with missing data (15), and reports that investigators deemed to have no patient safety event described within them (3). Of the remaining 415 reports, 320 contained one event, 82 contained two events, 11 contained three events, and 2 contained 4 events.

An example of a complex TAPS report containing multiple patient safety events is given below in figure 4.4, and the full text is presented as appears in the original report. The report was from a RRMA 2-3 participant. After error classification using the TAPS taxonomy (shown in section 4.9), the investigators assigned four classifications to this report. The TAPS classifications given were 2.1.4 (Diagnostic error), 2.2.1 (Medication management error), 1.3.3 (Medication dispensing error) and 1.5.2 (Communication error relating to hospital discharge summary).

Figure 4.4 TAPS report containing multiple error events including 2.1.4 (Diagnostic error), 2.2.1 (Medication management error), 1.3.3 (Medication dispensing error) and 1.5.2 (Communication error relating to hospital discharge summary).

<i>b) Related to a specific patient?</i>	YES
<i>c) How well do you know the patient?</i>	5 – Very well
<i>d) What is the patient's age?</i>	79
<i>e) What is the patient's sex?</i>	MALE
<i>f) Is the patient from a non-English speaking background?</i>	NO
<i>g) Aboriginal or Torres Strait Islander descent?</i>	NO
<i>h) What happened? Please consider what, where and who was involved.</i>	<p>I saw the patient following discharge from hospital following an admission with pneumonia. It was on a weekend with pathology and radiology services not available to me. The patient had just completed the short course of oral antibiotics prescribed on discharge. He reported a painful ankle which had been present for a week (it had been present, but not dealt with, during his admission). He had no past history of gout or other arthritis.</p> <p>On examination he had an acute mono-arthritis of his ankle. This needed immediate investigation (I considered partially-treated septic arthritis to be one of the differential diagnoses). He was sent back to the teaching hospital from which he had been discharged.</p> <p>I saw him again one and a half weeks later. His discharge summary recorded his diagnosis as "cellulitis". This was not consistent with the clinical picture on presentation or at this time (he still had pain and an effusion of his ankle clinically). His discharge summary recorded him as being on dicloxacillin. The patient wasn't on any antibiotics. He had a script for Keflex for the hospital pharmacy but had been told by the nurse discharging him (on a weekend, no doctor saw him prior to discharge) that there wasn't time to get this filled as his bed was needed urgently.</p> <p>I rang the hospital to try and sort out what was going on. The switch told me there was no way they could ascertain who the responsible resident or registrar (of the consultant under my patient was admitted) was. They could, however, refer me to the orthopaedic registrar on call.</p>

	The registrar told me that he wasn't involved in my patient's care, but was aware of this as an interesting case that had been discussed in clinical meetings. The patient had not been diagnosed as having cellulitis - the diagnosis was of a Charcot's joint. He didn't need to be on antibiotics.
<i>i) What was the result? Please think about actual and potential consequences.</i>	Apart from the distress of not knowing what was going on and his dissatisfaction re the discharge process, my patient suffered no ill-effects. But the appalling lack of communication (and disinformation) and difficulty accessing clinical information from the hospital put my patient at risk of adverse outcomes. The attitude of not filling scripts because of logistic difficulties not related to the patient's own care, in fact, benefited my patient as the treatment was inappropriate (a result of egregious lack of attention by the resident involved), but obviously has the potential to produce adverse outcomes.
<i>j) What may have contributed to this error? Please consider any special circumstances.</i>	I can only speculate as to how a resident could have got the diagnosis entirely wrong on a discharge summary when those not involved in the patient's clinical care were aware of the diagnosis and the clinical scenario was at odds with the diagnosis. Given previous similar experiences, I suspect understaffing, the trend to shift-work like rosters (i.e. diminished clinical responsibility for individual patients) and the imperative to throw sick patients out of beds on weekends may be factors.
<i>k) Where did the error happen?</i>	<i>Hospital</i>
<i>l) Was any patient harmed by this error?</i>	NO
<i>n) How often does this error occur in your practice?</i>	Sometimes (3–11 per year)
<i>o) What could have prevented this error? Please consider what could be done to prevent similar episodes in the future.</i>	A total overhaul of the organisation, staffing, funding and integration of the health-care system.
<i>p) Other comments?</i>	It is easy to apportion blame to individuals in this scenario. I am not privy to exactly how this error came about, but I suspect system rather than individual errors are of primary importance.

4.9 The TAPS Taxonomy

The TAPS taxonomy is a descriptive domain specific taxonomy. It has been recently published along with the results relating to the reviewer agreement and proportions of event types in the international journal *Quality and Safety in Health Care* (Makeham, Stromer et al. 2007). The full paper appears as Appendix 7 of this thesis, and the published taxonomy also appears in this thesis as Appendix 10.

The taxonomy has 3 levels of classification. The first level ('event type') relates to the underlying cause of the event, being either due to deficiencies in the process of delivering health care (type 1), or the knowledge and skills of health professionals (type 2). The second level has five groupings ('themes') within type 1 errors, and two groupings within type 2 errors. The five themes within type 1 are practice and health care systems, investigations, medications, non-medication treatments and communication. The type 2 themes are diagnosis and managing patient care. At the third level there are from 3 to 9 'descriptors' for each theme. .

4.9.1 Proportions of error events classified using the TAPS taxonomy

The TAPS taxonomy and the proportions of the 525 reported events that were classified from the study data using the TAPS taxonomy are shown on the following page in table 4.6, showing that 69.5% of events were process related (type 1), and 30.5% related to the knowledge and skills of health professionals (type 2):

Table 4.6 TAPS taxonomy with results of 525 patient safety events within 415 reports.

N	% of total	
365	69.5	1. Errors related to the Processes of Health Care
112	21.3	1.1. Errors in practice and health care systems
12	2.3	1.1.1 Errors relating to incorrect patient identification
15	2.9	1.1.2 Appointments and message handling errors
28	5.3	1.1.3 Patient record and filing system errors
25	4.8	1.1.4 Recall event and recall systems errors
6	1.1	1.1.5 Computer systems errors
6	1.1	1.1.6 Errors in the maintenance of a safe physical environment
7	1.3	1.1.7 Errors in provision of care after hours or inadequate staff coverage
4	0.8	1.1.8 Errors relating to patient confidentiality issues
9	1.7	1.1.9 Practice and health care systems errors not otherwise specified
65	12.4	1.2. Investigation errors
7	1.3	1.2.1 Errors relating to incorrect patient identification
12	2.3	1.2.2 Errors in the process of requesting investigations
9	1.7	1.2.3 Errors in the process of undertaking investigations
35	6.7	1.2.4 Errors in reporting processes or managing investigation reports
2	0.4	1.2.5 Investigation errors not otherwise specified
107	20.4	1.3. Medication errors
31	5.9	1.3.1. Electronic prescription writing or medication charting errors
16	3.1	1.3.2 Other prescription or medication charting errors
38	7.2	1.3.3 Medication dispensing and delivery errors
11	2.1	1.3.4 Patient self-administration of medication errors
11	2.1	1.3.5 Medication errors not otherwise specified
13	2.5	1.4. Treatment errors (non-medication)
11	2.1	1.4.1 Errors in the process of providing Immunisations
1	0.2	1.4.2. Errors in the process of undertaking procedures
1	0.2	1.4.3. Non-medication treatment errors not otherwise specified
68	12.9	1.5. Communication errors and process errors not otherwise specified
17	3.2	1.5.1. Errors in general communication with patients
31	5.9	1.5.2 Hospital discharge and other hospital based communication errors
9	1.7	1.5.3. Errors in referral to other health care providers
8	1.5	1.5.4 Errors in general communication with other health care providers
3	0.6	1.5.5. Communication and process errors not otherwise specified
160	30.5	2. Errors related to the Knowledge and Skills of Health Professionals
62	11.8	2.1. Errors in diagnosis
2	0.4	2.1.1. Errors in patient history taking
11	2.1	2.1.2. Errors in patient physical examination
27	5.1	2.1.3. Errors in investigations requested or their interpretation
22	4.2	2.1.4. Diagnosis related errors <i>not otherwise specified</i>
98	18.7	2.2. Errors in managing patient care
57	10.9	2.2.1 Medication management errors
9	1.7	2.2.2 Knowledge or skills errors in undertaking immunisations
13	2.5	2.2.3 Knowledge or skills errors in undertaking procedures
19	3.6	2.2.4 Errors managing care not otherwise specified

4.9.2 TAPS taxonomy coding guidelines

The guidelines for using the TAPS taxonomy were devised by the three coding investigators as the classification developed, and are presented below in table 4.7:

Table 4.7 TAPS taxonomy guidelines for coding patient safety events.

TAPS taxonomy guidelines for use
1. Consider the number of ‘patient safety events’ or separate elements that have contributed to a report describing a threat to patient safety, and classify each distinct patient safety event separately if there are more than one.
2. Consider the underlying cause to first code the event ‘type’ . Consider whether it should be considered as resulting from a breakdown in the ‘processes’ around patient care (type 1), or in the knowledge or skills base required for any person involved in the delivery of patient care (type 2).
3. Next assign the second level ‘theme’ of the patient safety event, choosing the most specific option from those listed within the assigned event type. (that is, from 1.1 to 1.5 for ‘type 1’ events, or 2.1 to 2.2 for ‘type 2’ events). <i>*For type 1 events, use theme 1.5 ‘Communication errors and process errors not otherwise specified’ when a more specific theme is not suitable.</i>
4. To complete, assign the most specific level 3 ‘descriptor’ available from within the second level theme chosen. In general, these descriptors are listed from more specific to less specific when moving down the list.

4.9.3 TAPS event types – ‘process’ versus ‘knowledge and skills’

When classifying an error event using the TAPS taxonomy, the fundamental decision to be made was the distinction between a type 1 or ‘Process’ type of event, versus a type 2 or ‘Knowledge and Skills’ related event. Essentially any event that was contributed to by a deficiency in the knowledge and skills of a person providing

clinical care to a patient involved in the incident was classified as a type 2 event, and all others fell into the type 1 category. The exception to this was a report in which there did not appear to be any error noted which were classified as ‘not an error’ in the brief description summaries.

The following two case studies are presented to demonstrate the different nature of a process event (type 1) to a knowledge and skills event (type 2). A synopsis of the salient features is given for each.

Figure 4.5 TAPS case study of a report containing a patient safety event relating to the processes of health care.

A patient with a background of developmental delay, epilepsy and schizophrenia attended a general practice regularly, but used two different surnames on different occasions, being the names of each of his divorced parents. The practice mistakenly held two different electronic records for him under these two names, which contained different medication lists. He was prescribed a new medication which resulted in him becoming over-sedated, lethargic and depressed as a result of an interaction with a medication listed in the other chart, before the mistake was discovered.

TAPS Code 1.1.3
Type Processes of health care
Theme Errors in practice and health care systems
Descriptor Patient record and filing system errors

Figure 4.6 TAPS case study of a report containing patient safety events relating to the knowledge and skills of health professionals.

A patient with severe depression was scheduled by their general practitioner (GP) to the regional psychiatric hospital. A week later the patient returned to the GP for follow-up after discharge. The patient reported to the GP that he had complained of increasing pain in the chest after admission to the psychiatric unit, and after some delay he was sent into the local base hospital by the psychiatric unit for a chest Xray without actually being physically examined. The chest Xray was normal, and after a further 3 days he was examined by a medical officer in the psychiatric unit and found to have a florid shingles rash. He was eventually sent home on analgesia, but antiviral management had not been appropriately instituted.

TAPS Code	2.1.2, 2.2.1 (2 events identified)
Type	Knowledge and skills of health professionals (both events)
Theme	Errors in diagnosis (event 1) Errors in managing patient care (event 2)
Descriptor	Errors in patient physical examination (event 1) Medication management errors (event 2)

4.9.4 TAPS event themes and descriptors

After categorising an event as either a type 1 or type 2 error, the next step was to decide on the ‘theme’ of the event, which was one of five descriptive categories within type 1, or two descriptive categories within type 2. Then within these themes were a varying number of sublevels of description, called ‘descriptors’ with 35 end-descriptors in all (see Appendix 10).

The pilot taxonomy is shown in Appendix 4 (Makeham, Dovey et al. 2002a). The main differences between the pilot and TAPS taxonomies at the second or ‘theme’ level of the type 1 process errors were the merging of payment errors and errors in healthcare workforce management into third level descriptors under the theme of ‘errors in practice and health care systems’, and the expansion of the treatment error

category into medication and non-medication treatment errors. The themes of the type 2 errors were greatly changed and simplified from the pilot to the TAPS taxonomy, with three categories under 'knowledge and skills' in the pilot becoming just two themes in the TAPS taxonomy. This was based on the logic that errors in knowledge and skills essentially related to either diagnostic or management issues, and the earlier categories of 'execution of a clinical task' and 'wrong treatment decision with right diagnosis' were very problematic for coding agreement. Finally, an addition into every theme was the end-descriptor category of 'not otherwise specified', which essentially allowed for the categorisation of all the reported events.

4.9.4.1 Type 1.1 - Errors in practice and health care systems

The theme of 'Errors in practice and health care systems' accounted for the largest proportion of reported error events when compared to the second level of TAPS taxonomy classifications. It was largely comprised of administrative process errors in general practice, but occasionally also arose from systems failures in the residential care and hospital setting affecting patients visiting GP participants in the study.

It ranged from problems with the front desk contact with the patient, through to bookings, filing records, arranging recalls for patients requiring follow-up of specific conditions, computer system breakdowns in practices, physical problems with practice buildings or fittings, confidentiality problems such as personal information being inadvertently faxed to a third unrelated party, inadequate staff coverage in practices, residential care or hospital settings, and physical problems with the practice environment such as broken steps or examination couches.

The reports that fell into the 'not otherwise specified' category had a mixture of health systems errors, such as payment problems at reception, incorrect billing procedures, incorrect certificates being issued, poor staff management processes, the absence of required equipment in the practice, incorrect level of placement of a patient into a residential aged care facility influenced by family financial constraints, budgetary constraints at local hospitals causing bed closures, and unacceptable waiting times for coronary angiograms for public hospital patients.

The major variations in this theme from the pilot taxonomy were firstly its expansion in name and nature, from 'office administration' to a wider range of errors in practice and other health care systems. Secondly, a series of changes were made at the third or 'descriptor' level. Additions included errors relating to patient identification, recall systems, computer systems, after hours care and inadequate staffing, patient confidentiality issues, and the not otherwise specified group. The pilot taxonomy categories of chart completeness and patient flow through the healthcare system were deleted as they proved to be quite confusing. Message handling and appointments were condensed into one group. A case study of this theme is presented below in figure 4.7. It demonstrates an example of a recall system error in the practice.

Figure 4.7 Case study of an error in practice and health care systems - recall error.

A patient presents with a breast lump which the GP thinks is non-malignant. The doctor asks her to come back in 6 to 8 weeks, but both patient and GP forget and she is not seen for another 4 months. When she returns to the GP at a later time, her lump is diagnosed as breast cancer for which she requires mastectomy and chemotherapy. The reporting GP states that their recall systems were inadequate.

4.9.4.2 Type 1.2 - Investigation errors

The third level descriptors of the 'Investigation error' theme in the TAPS taxonomy were substantially changed from the pilot study taxonomy, where essentially they had been comprised of two groups being 'laboratory' or 'diagnostic imaging'. Instead of these, the concept of the process by which any type of investigation is managed was adopted as the basis of the third level descriptors. Five new descriptors resulted in the TAPS taxonomy, being issues relating to patient identification, the requesting process, the process of undertaking the investigation, reporting processes or managing investigation reports, (such as a failure in the dictation or transcription of an investigation report, as opposed to the report being incorrect due to a problem with the knowledge required to correctly report an investigation), and finally the 'not otherwise specified' group. Errors in reporting processes or managing investigation reports (1.2.4 of the TAPS taxonomy, see table 4.6) comprised the major portion of the events occurring in the investigation error theme.

A case study of the investigation error theme is presented below in figure 4.8, demonstrating an error in the reporting process of an investigation.

Figure 4.8 Case study of an investigation process error - reporting processes.

Serial beta-HCGs are taken due to concerns that a patient does not have an ongoing pregnancy. Results obtained by phone from the lab on day 3 find the level has dropped. The patient is distressed and the GP refers her for further management of a potential miscarriage. When the hard copy result arrives later, it shows a rise in levels, to the patient's relief. The reporting GP determined that the technician had read out the wrong group of numbers on the pathology report.

4.9.4.3 Type 1.3 - Medication errors

The theme of medication errors was created in the TAPS taxonomy and given a group of five descriptors, in comparison to the pilot taxonomy where it existed as a single third level descriptor under 'treatment errors'. It comprised the second largest group of process errors, and its descriptors ranged from prescription writing or medication charting (with and without a computer), dispensing and delivery errors, and patient self-administration of medication errors.

The largest group of descriptors were the dispensing and delivery errors, which included pharmacists accidentally mislabelling or handing out a different medication to that prescribed, and nursing staff mainly in residential aged care facilities accidentally administering different medication to that which had been charted for the patient. This was closely followed by a large group of errors relating to incorrectly printing information on computer generated prescriptions, often as a result of accidentally clicking the wrong drug strength on a drop-down menu of medications on the GP's prescribing software, or as a result of having the incorrect patient file open whilst consulting, if the GP forgot to close off the file of the patient from the previous visit in their room. A case study of a medication process error is presented on the following page in figure 4.9, which demonstrates an accidental dispensing error in pharmacy.

Figure 4.9 Case study of a medication process error - dispensing error

A patient who had been taking Prothiaden 25mg, 2 nocte, was dispensed 75mg tablets in error at the pharmacy. She became unsteady on her feet and started getting sleepy before the error was picked up when she questioned the pharmacist.

4.9.4.4 Type 1.4 - Treatment errors (non-medication)

The fourth theme of type 1 error events in the TAPS taxonomy related to non-medication treatment errors, and applied to reported problems concerning some aspect of the process of providing a non-medication treatment to a patient, as opposed to type 2 treatment errors which involved some sort of clinical lack of knowledge or skill in performing a procedure or providing a non-medication treatment. It was largely comprised of systems failures around the delivery of immunisations, and also included a case of accidentally using unsterilised equipment in a procedure, and a case of failing to provide palliative care treatment in a timely manner due to time management problems in the practice.

A case study of an immunisation process error is presented below in figure 4.10, demonstrating problems with documentation processes leading to a treatment error.

Figure 4.10 Case study of a non-medication treatment process error – immunisation

A four year old child presented for routine immunisations, which were given correctly as per the standard schedule. At the consultation, the child's 'blue book' (immunisation record) was not present. When the 'blue book' was later found, it showed that these immunisations had been given on a previous occasion.

4.9.4.5 Type 1.5 - Communication errors and process errors not otherwise specified

The TAPS taxonomy theme of communication errors and process errors not otherwise specified was similar to the pilot taxonomy's communication errors section (see Appendix 4). There was some refinement of the descriptors, new additions of specific problems with hospital discharge and other hospital communication errors, and of specific problems with referrals to other providers. It was also broader than the pilot taxonomy's communication section in that it captured all 'not otherwise specified' process type errors.

The concept of 'communication failure' is very broad, and it could be argued that most reported errors actually contain some aspect of a breakdown in communication. Therefore it was intended that this general theme be used when the error was some type of process problem, but one of the earlier four more specific themes listed did not suit the situation. This rule is detailed in the taxonomy guidelines for use, described previously in section 4.9.2.

The largest proportion of this theme, and equal second as the largest group of reported errors at the third level, was due to hospital discharge and other hospital based communication errors. Many of these were concerning the interface between the emergency department and the GP, as well as poor discharge communications as patients left the hospital sector and returned to the community.

A case study of a communication process error is shown below in figure 4.11, giving a common example of hospital discharge communication problems with a patient, as well as a patient self-administration of medication process error.

Figure 4.11 Case study of a communication process error - hospital based

A patient is discharged from hospital with a 5 day supply of their medications. On review with their GP some days later it was realised that they had been taking both their original medicines in addition to the hospital supplied medications each day, resulting in double dosing.

4.9.4.6 Type 2.1 - Errors in diagnosis

Errors in diagnostic knowledge and skills of health professionals comprised around 12% of total reported events, and the main difference in this part of the TAPS taxonomy from the pilot taxonomy was that a need to assign blame to a particular health profession was removed for this section of the classification. The main justification for this was that in the original study design there was no perceived benefit in assigning blame to an individual clinician for a reported error, and so there was no question relating to this in the reporting process. As for all events, but most relevant for the type 2 errors, a reported error by definition was not necessarily the result of the reporter's actions. This meant that very often the information relating to fault was unavailable from the report, making the pilot taxonomy very difficult to apply. The TAPS taxonomy descriptors for this section were instead divided into the different elements of the diagnostic process, being history, physical examination and investigations.

In some instances, a type 2 diagnostic error was clearly being reported by the participant, but it was not always possible to determine from the written report where in the diagnostic process an error had occurred, and so the category of ‘diagnosis related errors not otherwise specified’ was able to capture these events.

As shown in the TAPS taxonomy proportions of error events in section 4.9.1 (see table 4.6), the majority of this group of events related to knowledge and skills deficiencies in the request or interpretation of investigations, and an example is given in the following case study shown in figure 4.12 demonstrating diagnostic problems with physical examination and a delay in requesting an investigation of a skin biopsy.

Figure 4.12 Case study of a knowledge and skills error in diagnosis

A non-healing ulcer on a man’s thumb is treated with dressings for a year initially on the advice of a surgeon, and when he sees the treating GP’s colleague, a biopsy is taken which shows a squamous cell carcinoma. He requires amputation of the thumb and develops a chest infection and acute heart failure post-operatively.

4.9.4.7 Type 2.2 - Errors in managing patient care

As a theme group, type 2 errors concerning the management of patient care was almost twice as common as diagnostic errors. The theme appears in the TAPS taxonomy as a replacement of the pilot taxonomy sections 2.1 ‘errors in the execution of a clinical task’ and 2.3 ‘wrong treatment decision with right diagnosis’ (see Appendix 4), however it does not have any of the same descriptors as these sections, both of which were found to be very confusing and poorly described in the pilot taxonomy. Instead the management of patient care is broken down into the

management of medication, the undertaking of immunisations, the undertaking of other procedures such as minor operations, and other patient care management errors.

An earlier version of the TAPS taxonomy also had a descriptor for errors in the provision of preventative care, however it was found that no reports were made relating to this subject, and so it was dropped from the final taxonomy.

Although knowledge and skills errors overall only accounted for about 30% of events, the most common group of reported error events at the third level of the taxonomy was medication management errors. A case study example of one of these is presented below in figure 4.13.

Figure 4.13 Case study of a knowledge and skills error in managing patient care - medication management

A GP prescribes tramadol for a patient on an SSRI, ignoring the computer prescribing software's warning about interactions. The patient develops symptoms of serotonergic syndrome and the medication is stopped after 2 days.

4.10 Coder agreement from pilot to TAPS taxonomy

Three GPs from the investigating team (Meredith Makeham, Simone Stromer and Charles Bridges-Webb) initially coded the set of 433 reports using the pilot taxonomy shown in Appendix 4 (Makeham, Dovey et al. 2002). After discussion, an initial draft of the TAPS taxonomy was created for testing, and as described in the methods, the

coders started the classification process again using approximately a quarter of the reports at a time.

The coders came together after each quarter of report coding to discuss coding issues and make adjustments to the working draft of the TAPS taxonomy, and specifically review cases in which there was a complete disagreement of classifications used by the three coders to reach a consensus on which classification should be applied (a minimum of two out of three coders in agreement). This process resulted in the production of the TAPS taxonomy (shown in Appendix 10) and its guidelines for use.

Using the final TAPS taxonomy, the last 132 reports in the dataset (approximately one quarter) were classified by the three coders, and the results presented below represent the classifications made prior to discussion of reports in which there was a complete disagreement (that is, cases where all three coders applied a different taxonomic classification to the report).

Using the kappa statistic, the percentage agreement of the three coders was compared from the initial level of agreement using the pilot taxonomy with the full set of 433 reports, to this final set of 132 reports using the TAPS taxonomy. The agreement amongst the three coders at each level of both the pilot and TAPS taxonomies, with corresponding kappa scores, are shown in table 4.8 on the following page:

Table 4.8 The proportion of agreement amongst the three coders and kappa score at each level of the taxonomies, comparing the pilot to the TAPS taxonomy.

Coding level	Taxonomy	Complete disagreement %	Two of three coders agree %	Complete agreement %	Kappa score
Level 1 (Type)	<i>Pilot</i>	2	28	70	0.59
	<i>TAPS</i>	0	10	90	0.82
Level 2 (Theme)	<i>Pilot</i>	14	45	41	0.48
	<i>TAPS</i>	1	34	65	0.72
Level 3 (Descriptor)	<i>Pilot</i>	26	49	25	0.37
	<i>TAPS</i>	8	34	58	0.66

A kappa score of between 0.40 and 0.75 indicates fair agreement. (Fleiss 1981; Bolton, Mira et al. 1997) The results show that this was not able to be achieved in the pilot taxonomy's third level of classification which had a kappa score of 0.37. Even in the second level of classification, the pilot taxonomy's kappa score is in the lower end of the range of fair agreement, at 0.48.

The TAPS taxonomy showed a marked improvement in coder agreement at all levels from the pilot taxonomy. At the first level, kappa agreement was highest at 0.82. The kappa score for the TAPS taxonomy was lower at levels 2 and 3, although remaining in the upper range of fair agreement. This decrease in coder agreement from level 1 to level 3 was as expected, because the number of choices for coding increased at each level, moving from two at the first level, to seven at the second level, and to

thirty five unique classifications at the third level. With this increasing number of choices, there was a far greater likelihood that coders would choose different options from chance alone, which in turn would lower the kappa statistic.

At the third level of the code from the pilot to the TAPS taxonomy, the proportion of reports in which at least two of three coders agreed rose from 74% to 92%, and the kappa score moved from 0.37 to 0.66, and as such the TAPS taxonomy falls within the fair agreement range based on the kappa statistic (Makeham, Stromer et al. 2007).

4.11 Patient related factors in reported errors

During the reporting process, a number of patient demographic details and other factors were recorded by the participants, results of which are presented in more detail in this section. These include whether or not a patient was involved in a report, how well the GP participant knew the patient on a 5 point rating scale, the average age of the patient as well as proportions relating to gender, Non-English Speaking Background (NESB) and Aboriginal and Torres Strait Islander peoples.

4.11.1 Patient involvement in reported errors

In answer to the question of whether or not the error being reported was related to a patient, participants answered 'Yes' in the majority of cases, being 385 of 433 reports (89%). Considering only those reports that contained at least one error event (415), a patient was involved in the error that was being reported 93% of the time.

In examining the 48 reports that were not associated with patient involvement and their types of events (as classified using the TAPS taxonomy), approximately one quarter were tests that had come in from participants after the official start of reporting had commenced, and the rest were type 1 events. (This is as would be expected from the nature of the taxonomy and the relationship of type 2 events to diagnosis of patients and patient care management issues, making it unlikely for a type 2 event to be reported that was unrelated to a patient.)

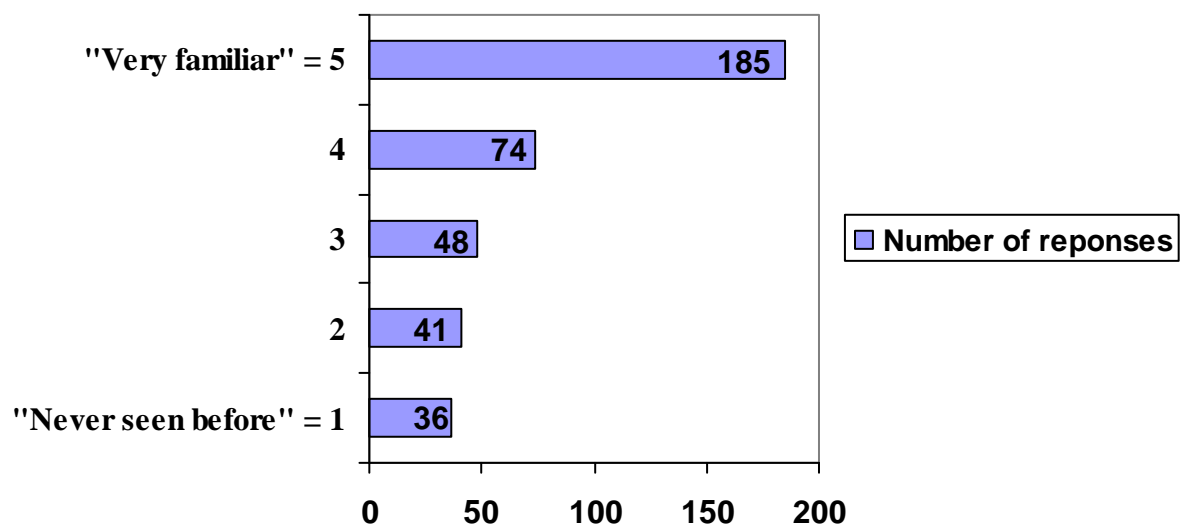
In terms of the type 1 themes, all five of the level 2 groups of the TAPS taxonomy were represented, but the majority of these non-patient reports were concerning the first theme of errors noted with practice and health care systems (16), such as computer system failures, followed by medication process errors (10).

4.11.2 How well the patient was known

Participants were asked to rate how well the patient was known on a scale of 1 to 5, where 1 was labelled “I have never seen this patient before and am not familiar with his/her health problems” and 5 was labelled “I am very familiar with this patient and his/her health problems”.

For all reports in which it was indicated that a patient was involved, the participants more commonly indicated that they were very familiar with the patient than that they had never seen them before. In one case, the question was left unanswered. Figure 4.14 on the following page shows the distribution demonstrating the trend of patient familiarity across the board.

Figure 4.14 The number of responses per each of five familiarity categories, rating how well the patient involved in an error was known to participants.



A further analysis of the responses given to this question was undertaken, in relation to the error types as classified by the TAPS taxonomy. There appeared to be a possible trend in the data, with reports in which the patient was said to have been well known being more commonly associated with the events being classified as type 2, knowledge and skills related. When the response was “5” (very familiar), 37% of events had been classified as type 2 as opposed to 26% when the response to the question was “1” (never seen before).

The data was firstly examined for an association between having never seen the patient before (“1”) versus any category of having seen the patient (>1), and the error type being process (type 1) versus knowledge and skills (type 2). Using Fischer’s exact test, there was no significant association between these outcomes at the 5% level ($p = 0.35$).

Next the results were examined for an association between having never seen the patient before (“1”) versus the category of knowing the patient very well (“5”), and the error type being process (type 1) versus knowledge and skills (type 2). Using Fischer’s exact test, again there was no significant association between these outcomes at the 5% level ($p = 0.25$).

4.11.3 Age of patients involved in reported errors

If an error was reported as relating to a specific patient, participants were asked to state the age of the patient in whole numbers. Descriptive statistics of the reported age of patients is presented below in table 4.9 for the 383 reports in which this figure was completed:

Table 4.9 Descriptive statistics relating to the age of patients in error reports.

Parameter	Value
Mean	51.9
Standard deviation (SD)	26.7
Standard error of the mean (SEM)	1.36
Number (N)	383
95% Confidence Interval	49.2 to 54.6
Minimum	0
Median	56
Maximum	104

The average age of patients involved in type 1 (process) events was 52.4 years (with a standard error of the mean (SEM) of 1.45), as compared to type 2 events in which the average age was 55.0 years, with a SEM of 2.26. There was no significant difference in these averages using the unpaired Student’s t-test at the 5% significance level ($p = 0.33$).

4.11.4 Gender of patients involved in reported errors

If an error was reported as relating to a specific patient, participants were asked to state the gender of the patient by clicking next to male or female on the web questionnaire. This was answered in 382 cases, with 169 responses of male (44%) and 213 responses of female (56%).

There appeared to be a possible higher proportion of male patients involved in type 2 (knowledge and skills) error events, with 49% of type 2 events involving male patients, versus 42% of type 1 events. A statistical analysis of the association between gender and type 1 (process) versus type 2 (knowledge and skills) was undertaken. Using Fisher's exact test, there was no significant association between gender and event type at the 5% significance level ($p = 0.22$).

4.11.5 Ethnicity of patients involved in reported errors

If an error was reported as relating to a specific patient, participants were asked to indicate if the patient was either from a non-English speaking background (NESB), and whether or not the patient was an Aboriginal and Torres Strait Islander (ATSI) person. In 385 reports in which a patient was said to have been involved, the participant identified the patient as NESB in 60 reports (16%), and ATSI in 6 (2%).

The proportions of type 1 and 2 events when comparing the NESB reports to non-NESB reports were almost identical, and no statistically significant association between event type and whether or not a patient was NESB was found at the 5% significance level using Fishers exact test ($p = 1.0$). However on considering the issue

of whether a patient was ATSI, of the 6 cases, there were twice as many type 2 events as type 1 events. This association was not quite statistically significant at the 5% level using Fisher's exact test ($p = 0.096$).

4.12 Event locations of reported errors

In answer to the question of where a reported error had occurred, there were ten options for the event location (office or surgery, nursing home, hospital, patient's home, telephone, emergency room, laboratory, pharmacy, radiology, and 'other'). Participants were able to answer with as many choices as they felt applicable.

First considering each error report as a single case, regardless of the number of events contained within it, there were 477 location selections made by participants in 433 TAPS reports. This included 16 reports where no location was selected (tests), 370 reports with 1 location, 37 reports with two locations, 7 reports with three locations, and 3 reports with four locations. The majority of the reports with two or more locations included office and one other, and of the ten reports with 3 or 4 locations, combinations of the office or surgery, patient's home, hospital and telephone were commonly involved.

In considering the association between event types and locations, it should be recalled that each report could contain one or more events, and so each event within a report was tagged with the location or locations that the participant had selected for this analysis. This resulted in the 525 error events being associated with 610 location counts, as again multiple locations could be associated with a single event. The overall proportion of type 1 to type 2 events within this group was 70% to 30%.

Table 4.10 on the following page shows the total number of reports with a particular location selected, the number of reports within this that had a second, third or fourth additional location selected (multiple locations), the number of type 1, type 2 and the total number of events associated with the location, and the proportion of type 1 to type 2 events associated with a given location.

The proportion of type 1 to type 2 events within each location was compared to the proportions of type 1 to type 2 events for all other locations combined, using Fisher's exact test. The probability that a given location's proportion of type 1 to type 2 events was significantly different from the remainder of the reports at the 5% significance level is presented as the 'p value' in the final column of table 4.10. This shows that there were significantly more type 2 events reported that were located in nursing homes than other locations, at 45% ($p = 0.05$), and significantly less type 2 events reported from pharmacies than other locations, at 7% ($p = 0.003$).

Table 4.10 The total number of locations chosen by participants within 433 TAPS reports; the number of counts of a given location within reports that were associated with a second, third or fourth location; location counts associated with type 1 and 2 events; the proportion of type 1 to type 2 events for each location; and the p-value of the proportion of type 1 to type 2 events for a given location compared to all others combined.

Location	Total Number location counts associated with reports (N= 477)	Number of location counts associated with other locations (N= 107)	Location counts associated with Type 1 events (N= 427)	Location counts associated with Type 2 events (N= 183)	Proportion of type 1 to type 2 events in a given location	Proportion of type 1 to type 2 events for all other locations combined	P-value
Office	271	35	233	93	0.71	0.68	0.43
Nursing Home	29	9	25	17	0.55	0.71	0.05
Hospital	66	17	61	36	0.64	0.71	0.19
Patient's Home	11	10	13	2	0.87	0.70	0.25
Phone	37	15	30	21	0.59	0.71	0.08
Emergency	5	3	6	3	0.82	0.70	1.00
Laboratory	14	8	14	3	0.82	0.70	0.42
Pharmacy	27	3	28	2	0.93	0.69	0.003
Radiology	11	5	10	5	0.67	0.70	0.78
Other	6	2	7	1	0.88	0.70	0.45

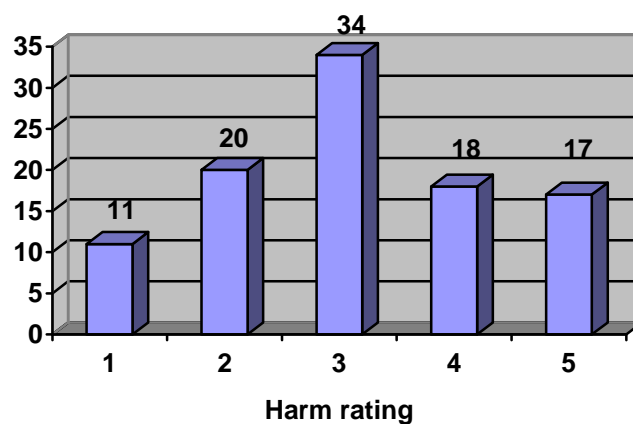
4.13 TAPS reports associated with patient harm

4.13.1 Patient harm ratings by participants in TAPS reports

When completing reports, TAPS study participants were asked the question “To your knowledge, was any patient harmed by this error?”. If they answered in the affirmative, they were then shown the question “How would you rate the seriousness of this harm?”, and given a 5 point Likert scale to click a number on from 1 to 5, with a label before the number 1 being “Not serious at all”, and after the number 5 being “Extremely serious”.

Within the group of the 415 error reports which contained at least one event, there were 100 reports (24%) in which the participant had given a positive response to the question of patient harm (harm positive). Within this, the frequencies of ratings given from 1 to 5 are shown below in figure 4.15.

Figure 4.15 The distribution of harm ratings (from 1 to 5) within the 100 reports containing at least one error event, in which patient harm was stated to be positive by the participant.



4.13.2 Reported patient harm in relation to TAPS event classification

The association between harm positive reports and their TAPS taxonomy classifications were considered in a number of ways. Firstly, to evaluate the first level event type 1 or 2 and its association with harm, each of the 415 reports was grouped into either a type 1 category, a type 2 category, or a 'mixed' category if both type 1 and 2 events were present within the same report. This resulted in a frequency of event types as shown below in table 4.11.

Table 4.11 The frequency of type 1, type 2 and mixed event types in reports

Event type	Frequency
1	275 (66%)
2	109 (27%)
Mixed	31 (7%)
Total	415 (100%)

The association between these categories of event types and patient harm being reported as positive is shown below in table 4.12.

Table 4.12 The frequency of harm positive reports within TAPS taxonomy event types 1, 2 and mixed.

Event type	Frequency of harm
1 Errors related to the processes of health care	41/275 (15%)
2 Errors related to the knowledge and skills of health professionals	42/109 (39%)
Mixed event types 1 and 2	17/31 (55%)
Total	100/415 (24%)

Event type 1 had the lowest rate of harm (15%), with mixed events resulting in the greatest rate of harm (55%). There was very strong evidence of a difference in rates of reported harm between the types of event ($\chi^2=41.13$, $P<0.0001$).

Next, the association between the number of events within reports and frequency of reports being harm positive was considered, with the results summarised in table 4.13.

Table 4.13 Association between number of events and harm in the 415 TAPS reports.

Number of events	Frequency of harm
1	65/319 (20%)
2	33/84 (39%)
3 or 4	2/12 (17%)
Total	100/415 (24%)

There was strong evidence of a difference in rates of harm by the number of events ($\chi^2=13.37$, $P=0.001$), with reports containing two events having the highest association with being reported as involving patient harm.

In order to examine the association between harm positive reports and their TAPS taxonomy classifications at the second or ‘theme’ level, each of the 525 TAPS events contained within the 415 TAPS reports was labelled with as ‘harm positive’ or ‘harm negative’, corresponding to the harm result that the overall report was given by participants. This resulted in 138 counts of patient harm within the 525 separate error events (26%) that were contained within the 415 reports. This then enabled an

evaluation of the association between harm positive reports and the second level or theme of events, of which there are seven main groupings (five under type 1 and two under type 2). The frequency of harm positive reports within each of the second level themes is presented below in table 4.14:

Table 4.14 The frequency of harm positive events per TAPS theme for the 525 error events within 415 reports, the frequency of harm positive events for all other themes combined, and the p-value of the frequency of harm positive events for a given theme compared to all other themes combined.

Event theme	Frequency of harm positive events within each theme	Frequency of harm positive events for all other themes combined	P value
1.1 Errors in practice and health care systems	20/112 (18%)	118/413 (29%)	0.022
1.2 Investigation errors	11/65 (17%)	127/460 (28%)	0.072
1.3 Medication errors	11/107 (10%)	127/418 (30%)	<0.0001
1.4 Treatment errors (non-medication)	3/13 (23%)	135/512 (26%)	1.00
1.5 Communication and process errors NOS	25/68 (37%)	113/457 (25%)	0.039
2.1 Errors in diagnosis	28/62 (45%)	110/463 (24%)	0.0006
2.2 Errors in managing patient care	40/98 (41%)	98/427 (23%)	0.0005
Total	138/525 (26%)		

The proportion of harm positive to harm negative events within each theme was compared to the proportions of harm positive to harm negative events for all other themes combined, using Fisher's exact test. The probability that a given theme's proportion of harm positive to harm negative events was significantly different from

the remainder of the themes at the 5% significance level is presented as the 'p value' in the final column of table 4.14.

This shows that for themes 11 (Errors in practice and health care systems) and 13 (Medication process errors), there was a lower proportion of harm positive events, and for themes 15 (Communication errors and process errors not otherwise specified), 21 (Errors in diagnosis) and 22 (Errors in managing patient care) a higher proportion of harm positive events, than in all other themes combined at the 5% significance level.

4.13.3 Reported patient harm in relation to patient age

The average age of patients involved in reports that were harm positive was compared to reports in which participants reported that there was no patient harm. There were 284 reports in which an age was provided, and patient harm was stated to be negative and 96 reports in which an age was provided, and patient harm was positive. In four reports, there was positive patient harm but no patient age provided. The descriptive statistics for the average age of patients in the 380 reports in which age was provided, and harm was noted as positive or negative, are presented below in table 4.15, showing an average age of 49.8 versus 58.2 in harm negative versus harm positive reports.

Table 4.15 Descriptive statistics for the average age of patients in harm negative versus harm positive reports.

Parameter	Harm negative	Harm positive
Mean	49.9	58.2
Standard deviation (SD)	25.9	27.6
Standard error of the mean (SEM)	1.54	2.82
Number (N)	284	96
95% Confidence Interval	46.8 to 52.9	52.6 to 63.8
Minimum	0.4	0
Median	53	66
Maximum	100	104

These averages were then compared using the Student's t-test, which showed that the difference in mean age of patients involved in harm positive to harm negative reports was highly statistically significant ($t = 2.68$, $DF = 278$, $p = 0.0076$), with older patients more commonly being involved in harm positive reports.

4.13.4 Reported patient harm in relation to patient gender

There were 380 of 415 reports in which a patient gender was selected, and harm was reported as positive or negative, and 4 reports in which harm was indicated as positive, but no gender selected. The proportions of male and female patients involved in reports that were harm positive and negative are presented below in table 4.16.

Table 4.16 The proportions of female to male patients in harm positive and harm negative TAPS reports.

Patient harm reported	Female patients	Male patients
YES (%)	51 (53%)	45 (47%)
NO (%)	162 (57%)	122 (43%)

These proportions were then compared using Fisher's exact test, which showed that the association between gender and harm was not statistically significant at the 5% significance level ($p = 0.55$).

4.13.5 Reported patient harm in relation to ethnicity (NESB)

There were a total of 60 reports in which one or more error events occurred and participants indicated that a patient of non-English speaking background (NESB) was involved. The number and percentages of NESB to non-NESB patients involved in reports in which harm was deemed positive or negative by participants is shown below in table 4.17.

Table 4.17 The proportions of non-English speaking background (NESB) to non-NESB patients in harm positive and harm negative TAPS reports.

Patient harm reported	NESB patients	Non-NESB patients
YES (%)	13 (13%)	87 (87%)
NO (%)	47 (15%)	268 (85%)

These proportions were compared using Fisher's exact test, showing that there was no significant association between patient harm and patient's being NESB at the 5% significance level ($p = 0.7448$).

4.13.6 Reported patient harm in relation to Aboriginal and Torres Strait Islander (ATSI) peoples

There were a total of 6 reports in which one or more error events occurred and participants indicated that they identified the patient as Aboriginal and Torres Strait Islander (ATSI). The number and percentages of ATSI to non-ATSI patients involved in reports in which harm was deemed positive or negative by participants is shown below in table 4.18.

Table 4.18 The proportions of Aboriginal or Torres Strait Islander (ATSI) patients to non-ATSI patients in harm positive and harm negative TAPS reports.

Patient harm reported	ATSI patients	Non-ATSI patients
YES (%)	3 (3%)	97 (97%)
NO (%)	3 (1%)	312 (99%)

These proportions were compared using Fisher's exact test, showing that there was no significant association between patient harm and patient's being ATSI at the 5% significance level ($p = 0.154$). This is based on a very small number of cases however, and so the trend shown in table 4.18 above towards a higher proportion of harm reported in association with ATSI patients may become significant with a larger number of reports.

4.14 Preventability of reported errors

In almost all TAPS reports, preventive strategies were offered by participants in the free text response to the question of whether there were any factors that may have prevented this or any other similar error events. There were 9 of 415 TAPS reports (2.2%) containing 10 of 525 error events (1.9%) in which participants had either no response or a negative response in their answers to this question.

On review of each report by the Chief Investigator (Meredith Makeham) regarding the question of preventability, preventive strategies were considered possible in 4 of the reports in which participants had not suggested anything, reducing the number of reports in which no preventive strategies could be suggested by either participants or the Chief Investigator to 5 of 415, or 1.2%.

The types of preventive suggestions provided by participants in the most part related to the specific detail of the error that was raised in the report. There were three main types of preventive suggestions raised, and these were irrespective of whether the report was a result of the participant's own actions or those of other parties.

The first were suggestions related to personal practices, or personal learning goals. For example, a failure to use the computer file of the patient in the consulting room because the previous patient file was still open would have a comment such as "Be more vigilant in changing from previous patient's file to file of patient now in consulting room", or a case of supra-patellar bursitis due to poor injection technique had a comment of "improve my injection technique".

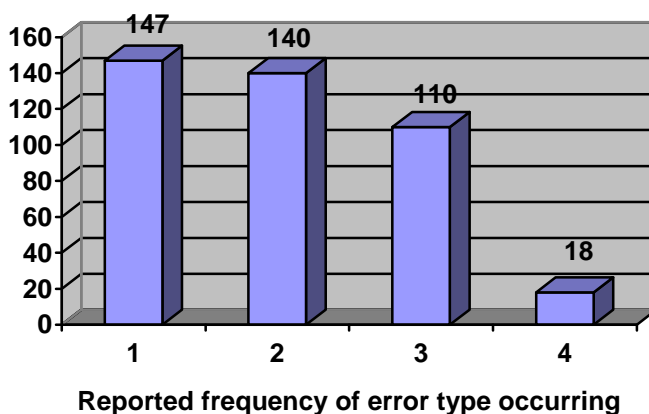
The second related the systems in place at the location where an error occurred, such as the general practice or communications from the local hospital. For example, a failure to recall a patient for review of a serious medical condition would have the suggestion “Need to improve our practice recall system”, or a failure to provide adequate follow-up treatment due to poor communication from the hospital resident such as after the initiation of warfarin had the suggestion “Hospitals need to use a separate sheet for charting warfarin. That sheet should include the hospital protocol for initiating warfarin, INR results and daily warfarin dose. That sheet should be attached to the discharge summary.”

The third type of suggestions related to the wider health system, such as a case of a mental health patient having inadequate assessment and treatment having the comment “Proper assessment at hospital. More bed space and more staff for mental health area.” Another example was a case of an elderly lady being discharged from the local hospital Emergency Department when the GP sent her in after a fall due to her being at high risk of further injury and requiring assessment and rehabilitation. Within hours of being sent home she had a further fall and hip fracture, requiring operation and months of further treatment and care. The GP commented that this could possibly have been prevented if “GP referrals to admitting officer of public hospital (got) a higher priority than they does. Public hospital 'closed bed' policy (should) be reviewed - a budget constraint. Bed block in the Emergency Department secondary to closed bed policy.” A similar type of report had the comment “Sending home elderly unstable patients after hours is risky as support services can't be put in place after hours, consider keeping them til (*sic*) morning.”

4.15 Reported error types considered to occur frequently in general practice

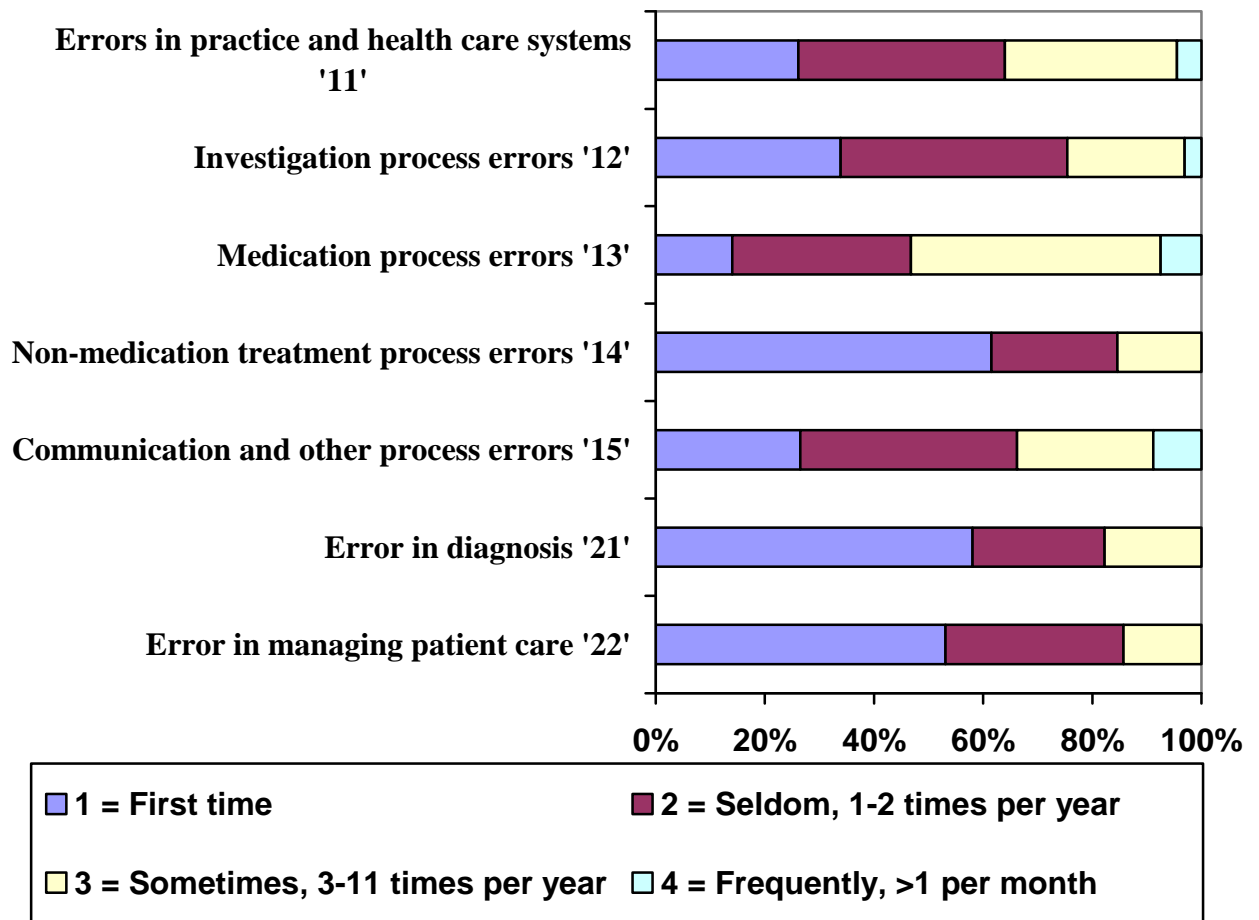
Participants were asked to indicate within four main groups how frequently they felt that the type of error that they had just reported occurred in their daily practice. The groups were labelled on the questionnaire as “1 = first time”, “2 = seldom, 1-2 times per year”, “3 = sometimes, 3-11 times per year”, and “4 = frequently, >1 per month”. The distribution of reported frequencies of error types within the 415 reports which contained at least one error event are presented on the following page in figure 4.16.

Figure 4.16 The distribution of reported frequency of error type occurring (with 1 = first time, 2 = seldom, 1-2 times per year, 3 = sometimes, 3-11 times per year, 4 = frequently, >1 per month) within the 415 reports containing at least one error event.



In order to consider the association between the second level of error classification (or ‘theme’ of the event) and the reported frequency of error type occurring, each of the 525 identified error events were tagged with the frequency of occurrence score from 1 to 4 (detailed in section 3.18) that was associated with the report in which the event occurred. The resulting proportions of frequency of occurrence scores within each theme are presented visually on the following page in figure 4.17, showing that type 2 events were felt by participants to be occurring for the first time more often than type 1, with no counts of the ‘frequent’ category being selected for either diagnostic or patient management errors related to the knowledge and skills of health professionals.

Figure 4.17 The proportion of events per frequency of error occurrence category, with four categories ranging from 1 = first time to 4 = frequently, >1 per month.



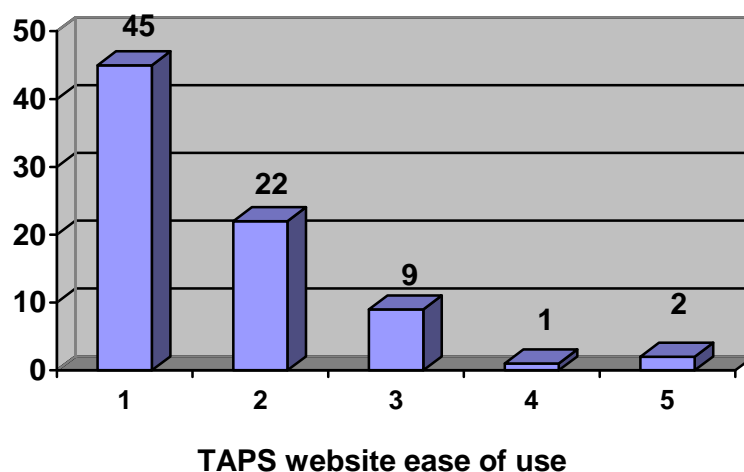
4.16 Participant feedback interview

After the completion of the TAPS study 12 month data collection period, 82 of the original 84 participants completed a 12 month feedback interview conducted by phone. The two participants who were not able to be followed up had left the study, one due to personal reasons and one moving interstate during the study period.

In addition to the earlier analysis of the 12 month feedback questionnaire regarding whether or not participants had submitted a report included in the quantitative analysis in section 4.4, other responses analysed were questions relating to the ease of use of the TAPS website ranked from 1 to 5, how many minutes it took to submit an online report, and the proportion of participants who said they would be more or less likely to report errors if the process had not been anonymous.

The participants were asked if they had sent any reports (to which 79 had reported YES), how had they found the website in terms of its ease of use, and asked to rank from 1 to 5, where 1 was easy and 5 was difficult. The results of this question are presented below in figure 4.18, showing that the majority of users felt that the site was easy to use.

Figure 4.18 Participant rating of the ease of use of the TAPS website from 1 (= easy) to 5 (= difficult).



The participants were also asked if they felt that they would have been more likely or less likely to have sent a report if the system had not been anonymous, and overall the

feeling was that anonymity supported error reporting. 52 answered that they would be “less likely” to report if not anonymous (66% of those who sent reports), 23 participants answered “no difference” (29%), no participants answered “more likely” and 4 participants (5%) said it would depend on the purpose of the system, such as if it were only for research.

The question “About how many minutes did it take you to send an on-line error report?” was answered by 76 of the 79 participants who sent reports. Three participants who had said they had sent reports were not able to estimate the time taken for submission. The results relating to the 76 responses are presented below in table 4.19, with an estimated average of 6.2 minutes for each report.

Table 4.19 Descriptive statistics relating to the time in minutes taken to submit an error report.

Parameter	Value
Mean	6.20
Standard deviation (SD)	3.99
Standard error of the mean (SEM)	0.46
Number (N)	76
95% Confidence Interval	5.29 to 7.11
Minimum	1
Median	5
Maximum	15

4.17 Reports involving patient deaths

The eight reports in the TAPS study which involved a patient death are discussed in more detail in this section of the thesis, in terms of the types of errors that were involved and the prevention messages that emerge. They represent an extreme level of patient harm arising in a health care setting. All of these eight reports had a positive response from participants to the question of whether harm had occurred, and all but two were rated at 5 out of 5 for severity of harm, with one rated 3 and another 4, explained in the reports as due to balancing other factors such as quality of life issues. These aspects will be discussed in more detail in section 4.17.2.

4.17.1 Types of reports as classified by the TAPS taxonomy

The proportion of reports involving a patient death contained more coded error events on average than the rest of the TAPS reports, with 50% having more than one event classification assigned. Four of the reports had one event, two had two events, and two had three events. This is an extremely small sample, and so further statistical analysis of this probable trend was not undertaken, however it would appear that these reports may be more complex generally than others in the data set.

All of the reports involving a patient death contained at least one type 2 (relating to the knowledge and skills of health professionals involved in patient care) TAPS taxonomy classification, and of the 15 error events contained within these reports, 11 were of type 2 (73%) in comparison to the 30% of all events in the data being type 2. At the theme level, the type 2 errors were fairly evenly spread between diagnostic (2.1) and patient management (2.2) errors, with six and five events respectively.

Three of the four events in this group which were type 1 (relating to the processes of providing patient care) were theme 5 (communication errors), two being 1.5.1 (failures related to patient communication) and one being 1.5.2 (hospital communication). The other was relating to the process of managing investigation results (1.2.4), in the case of responding to a high INR reading in a warfarinised patient.

4.17.2 Brief descriptions of TAPS reports involving a patient death

A brief description of the eight reports is provided on the following page in table 4.20. This shows that five of the reports in some way involved medication error, two of these cases being Warfarin related. The harm levels given by the reporting GP are also presented.

Table 4.20 TAPS report descriptions of cases involving a patient death, presented with the level of patient harm assigned by participants.

Report Number	Harm level	Description
100	5	Clindamycin caused renal problems in hospital. This was not communicated to the reporting GP upon discharge and the outcome was eventually that the patient had a premature death from renal failure.
112	3	A misdiagnosis of bacterial pneumonia in a nursing home patient, reporting GP felt patient was under investigated and treated, but balanced this decision and the outcome against probable increased patient suffering if they had been sent to hospital for further investigation and treatment.
153	4	Premature death from congestive cardiac failure/cardiomyopathy, with the severity of disease being underestimated. The reporting GP felt that the patient was inadequately investigated and managed.
222	5	A failure to diagnose a sub-arachnoid haemorrhage in a patient with persistent headache resulted in their death.
344	5	Patient death was from a haemorrhage due to a high INR, resulting from a drug interaction. No advice was given to the patient to have early an early INR check, and then a further mistake occurred in responding to a high INR reading.
360	5	Patient death was probably due to a high INR in patient who refused to follow the GP advice given on a home visit and go to hospital for further management.
402	5	Patient death was from congestive cardiac failure and renal failure due to the use of a Cox2 Inhibitor. The reporting GP felt that the patient may not have been aware of the potential risks of the medication and in hindsight they could have tried other analgesics.
442	5	Patient death was from multiorgan failure after the delayed diagnosis of pancreatitis as a side effect of an antibiotic (Klacid) in a patient who was also immune compromised.

4.17.3 TAPS case study involving imminent patient death

One other TAPS report deserves mention with respect to patient death, as it was assumed by the reporting GP that death was imminent although the outcome was unknown when the report was made. It is a particularly Australian example of community error, as it illustrates a case of communication failure and a health system that failed a patient identified as an Aboriginal and Torres Strait Islander person. The reporting GP wrote the majority of the story in the “what happened” text box, and further commented that better education and use of an aboriginal health worker in the original referral might have prevented the outcome described. The story is presented below in figure 4.19 in the words of the reporting GP, located in a RRMA 4-7 setting.

Figure 4.19 Case study of a TAPS report involving imminent patient death.

What happened?

“A poorly educated 38 year old aboriginal woman was admitted to our local hospital. She had hypercalcaemia, grossly raised tumour markers and metastatic deposits throughout her skeletal survey. Three years previously she had been referred to a specialist after discovery of a mass and abnormal radiology. She had defaulted from this appointment. Why, I have been unable to determine.

On discussion with her on her admission (she was informed) that she was seriously unwell and would require further investigations and scans to determine why she was so unwell. She objected to any more investigations and requested to be discharged. Apparently her family were away. Even explaining that she may well have cancer and would become increasingly unwell after discharge, she left and has declined further contact with medical services.

There are many problems here...relating to Aboriginal health beliefs about cancer, being dealt with by white medical services and the cultural backdrop to sophisticated high tech medicine. If she had been persuaded to accept help originally, she might have a normal life expectancy. If she accepted help now, she might live another 6 months to 2 years with chemotherapy. Currently she will die within days or weeks.”

4.18 Summary of results in relation to aims of the TAPS study

The four major aims of the TAPS study were presented earlier in this thesis in section

1.3. The results presented have addressed these aims in a number of ways, as follows:

- 1.** The design of a web-based, secure and anonymous error reporting system was completed. As presented in results of the participant feedback interview in section 4.16, the resulting system was found to be suitable in terms of access (79 of 82 participants submitted an online report) and ease of use (67 of 82 reported category 1 or 2 on a five point Likert scale measuring ease of use, with 1 being 'easy' and 5 being 'difficult'). The participant group were shown to be representative of NSW GPs (Makeham, Kidd et al. 2006).
- 2.** The incidence of reported error was determined, as presented in section 4.6, and these results were the first (and only to date) published in the world scientific peer reviewed literature on the incidence of reported error in a representative sample of GPs given a secure and anonymous electronic error reporting system (Makeham, Kidd et al. 2006).
- 3.** The TAPS taxonomy was used to quantify the proportions of error types reported by GPs, presented in section 4.9, and these proportions were the first published in the scientific literature based on a representative sample of GPs (Makeham, Stromer et al. 2007).
- 4.** A taxonomy was created to describe reported error in general practice, presented in section 4.9 and Appendix 10. It was found to have a good level of inter-coder agreement as presented in section 4.10. It has been suggested in the scientific literature that it would be possible to adapt the TAPS taxonomy as a tool for GPs to self-code error (Makeham, Stromer et al. 2007).

5 Discussion

5.1 Overview

In this section of the thesis, a discussion of the results of the TAPS study and their interpretation is presented. The key findings of the study are presented in section 5.2. Further discussion relating to the quantification of error reporting is presented in section 5.3. The creation of the TAPS taxonomy and features of error types contained within it are discussed in section 5.4. The measurement of patient harm in reported errors is discussed in section 5.5. Preventability of error is discussed in section 5.6, and other features of reported errors that were measured including patient related factors such as demographics are discussed in section 5.7. Future directions in the use of error reporting as feedback and learning tools for GPs are discussed in section 5.8. The strengths and weaknesses of the study methodology are discussed, with particular reference to existing literature addressing the reporting threats to patient safety in community settings.

5.2 Major outcomes and key findings of the TAPS study

The major outcomes and key findings of TAPS study are as follows:

- The TAPS study presented the first calculations known worldwide of the incidence of reported error in a general practice setting using a representative random sample of general practitioners. It was found that if an anonymous, secure, web-based reporting system was provided, the incidence of reported error per Medicare patient encounter item was 0.078% (95% CI 0.076% to

0.080%), and the incidence of reported error per patient seen per year was 0.240% (95% CI 0.235% to 0.245%) (Makeham, Kidd et al. 2006).

- The TAPS study created a simple descriptive general practice based error taxonomy, and is the first and only study to date to test the reproducibility of the application of such a tool using a group of general practitioners. The TAPS taxonomy was has a good level of inter-coder agreement (Makeham, Stromer et al. 2007).
- The TAPS study found that the majority of reported patient safety events were errors related to the processes of health care (type 1), rather than errors related to the knowledge and skills of health professionals (type 2), at 69% and 31% respectively at the first level of the TAPS taxonomy (Makeham, Stromer et al. 2007).
- At the second level of the TAPS taxonomy, five type 1 themes were identified: health care systems (21%); investigations (12%); medications (20%); other treatments (3%); and communication (13%). Two type 2 themes were identified: diagnosis (12%) and management (19%). Level three comprised 35 descriptors of the themes (Makeham, Stromer et al. 2007).
- The TAPS study created a secure anonymous web-based error reporting system suited to the Australian general practice setting (Makeham, Kidd et al. 2006). The majority of participants found the process easy to undertake, and took approximately 6 minutes to send a report.

- The TAPS database management system created an electronic method for managing and analysing a wide variety of features related to large numbers of anonymously reported errors from the Australian general practice setting.
- The majority of errors reported in the TAPS study had the direct involvement of a patient (93% of error reports). Overall the reporting general practitioners were very familiar with these patients, who were on average 52 years old, and more often female (56%).
- Approximately one quarter of the errors reported in the TAPS study was associated with patients being harmed. Reports containing events related to processes of health care were associated less frequently with harm than those containing events related to the knowledge and skills of health professionals.
- In reported errors associated with patient harm, the patients were on average older than patients in reports where no harm was known to have occurred (58 years versus 50 years respectively, $p = 0.0076$). There was no statistically significant difference found between these groups with respect to gender or ethnicity, including people from Non-English speaking backgrounds or Aboriginal and Torres Strait Islander peoples.
- Patient death was reported in 8 of 415 errors reported in the TAPS study (2%). In contrast to reports not involving patient death, these reports more often involved events relating to the knowledge and skills of health professionals (type 2) than events relating to the processes of health care (type 1).

- Anonymity is an important factor in medical error reporting systems. Two thirds of participants agreed that anonymity made them more likely to participate in reporting.
- The TAPS study provided a self directed learning educational activity for Australian general practitioners that was approved for 30 group 1 Quality Assurance and Continuing Education points by the Royal Australian College of General Practitioners (RACGP).
- The TAPS study highlighted a systematic error relating to immunisation failures with meningococcal vaccines which was reported to relevant organisations including NSW Health, the RACGP and the manufacturer involved, which was addressed with educational materials for GPs being distributed and communications in Australian Family Physician (Makeham, Kidd et al. 2004).

5.3 The quantification of error reported by general practitioners

Original research on errors in the primary care setting consists of a relatively limited number of studies, which have focused on qualitative descriptions of errors (Elder and Dovey 2002). The TAPS study provides the first calculated incidence of reported error from a random representative sample of GPs. Despite the small sample size, these findings can be generalised to NSW GPs, as there were no statistically

significant differences between the age, sex, and Medicare billings of TAPS participants and the source population from which they were sampled.

It may be concluded from the incidence findings that approximately one error was reported for every 1000 patient encounter related Medicare items billed per year, and approximately 2 errors were reported for every 1000 individual patients seen by a GP per year (Makeham, Kidd et al. 2006).

The results also indicate that using a secure encrypted website with an anonymous reporting method is a practical way of collecting error information from general practitioners, as at least 94% of doctors who enrolled in the study reported sending at least one report. This method may be a way forward in developing suggestions in the literature that an error database in general practice should be established (Sheikh and Hurwitz 2000; Sheikh and Hurwitz 2001; Runciman 2002).

The TAPS study provides an estimation of the incidence of reported errors in the general practice setting, but this should not be interpreted as the actual number of threats to patient safety that occur in the community. It is very difficult to assess the proportion of errors that go unreported, especially with an anonymous reporting system. Apart from deliberate under-reporting of errors that may arise through fear of litigation or lack of time to submit reports, a GP may not be aware that an error has even occurred. GPs have been found to have under-reported adverse drug events (Moride, Haramburu et al. 1997), suggesting other patient safety threats may also be under-reported.

The incidence of adverse events found in hospital settings has been reported to be orders of magnitude greater than the incidence of reported error found in the general practice setting of the TAPS study (Brennan, Leape et al. 1991), (Wilson, Runciman et al. 1995). Direct comparison is difficult to make, however this difference could be explained by considering the different methodologies used, and further consideration of their differences in findings relating to patient harm are considered later in section 5.5. These studies counted adverse events per hospital admission, rather than per single patient encounter with a doctor, as our Medicare item count approximated. A single admission may involve encounters with staff in a hospital many numbers of times, and so the potential for a single error to occur could be many times greater. In addition, these studies used a different definition of ‘error’, and a different method of counting error, by retrospective record review. This could impact upon the rates at which errors are noted in comparison to prospective self-reporting.

Anonymity was of major importance in our methodological design, to encourage reporting. In the past there has been a reluctance of health professionals to address the problem of errors due to feelings of guilt and a desire to avoid disapproval from colleagues (Kidd and Veale 1998). However, the use of a self-chosen PIN which was unknown to investigators led to some difficulties in interpreting the number of reports per GP, as the researchers were unable to assist if a PIN was forgotten. In addition, there was no way of knowing absolutely how many GPs submitted a report or changed their PIN during the study. This is likely to have lead to an underestimate of the numbers of reports per participant, as a result of decreased average number of reports per unique PIN.

The number of individual Medicare items billed relating to a patient encounter are the best approximation that could be made of separate patient encounters, but should not be interpreted directly as such. These counts do not always represent separate consultations, as the doctor may claim more than one item within a single visit. It is not possible to estimate how often this may have occurred from our data.

Consultations may also have occurred which were not billed, charged to the patient privately, or charged to the Department of Veterans Affairs, which keeps its data separately from the General Practice Branch of the Australian Government Department of Health and Aging.

There are no published studies on the incidence of reported error that are directly comparable to that found in the TAPS study, which was lower than hypothesised. In comparison to the Australian pilot study, the higher incidence of reported error may be due to volunteer bias and the non-representative nature of the participants (Makeham, Dovey et al. 2002). The authors of a US study showing an error rate close to 25% stated that their results were not generalisable due to limitations of the study (Elder, Vonder Meulen et al. 2004). In this study, only a small group of 15 doctors in 7 practices made reports, completing a review form after every consultation during three half day sessions. A UK study reporting an error rate of 7.6% was based on a two week collection of errors from ten practices in a single city (Rubin, George et al. 2003). However, a major difference is that this result was based upon a collection of reports from a large cross-section of staff working in general practice, with 163 people able to submit reports, and a higher proportion of participants with administrative rather than clinical roles.

The TAPS study method of prospective self-reporting returned a higher rate of error detection than a US study using retrospective record review in eight primary health care clinics (Fischer, Fetters et al. 1997). Once again direct comparison is difficult, as only medical adverse events were counted in this work, rather than errors using the broader definition of the TAPS study.

If a practical method of error reporting in primary care is to be instituted, retrospective record review would not offer the potential for use as an active learning tool. A prospective electronic reporting tool could be enhanced with the addition of feedback to the user and links to educational activities, plus have the scope to allow many other stakeholders in primary care settings to contribute error information.

5.4 A descriptive classification for safety events in general practice - The TAPS taxonomy

There is little information available on the proportion of types of patient safety events that are reported in general practice settings, and no taxonomy that is widely used by general practitioners (GPs) to describe these events.

Previous studies in primary care have described the relative proportions of different types of patient safety events that have been reported by their participants (Ely, Levinson et al. 1995; Britt, Miller et al. 1997; Fischer, Fetters et al. 1997; Bhasale, Miller et al. 1998; Dovey, Phillips et al. 2003c; Rubin, George et al. 2003; Wilf-Miron, Lewenhoff et al. 2003; Elder, Vonder Meulen et al. 2004; Phillips, Bartholomew et al. 2004; Rosser, Dovey et al. 2005), however none have been based

upon a representative sample of primary care clinicians contributing data. This makes generalisation of their results to the wider clinical setting difficult in comparison to the TAPS study, which is the first to include a representative sample of reporting GPs. In addition, the method of error classification varies markedly between these studies, further hampering direct comparison.

In recent years, a small number of taxonomies of patient safety events related to a general practice setting have been proposed (Dovey, Meyers et al. 2002; Elder and Dovey 2002; Makeham, Dovey et al. 2002; Rubin, George et al. 2003), all based upon patient safety event reports collected from small non-random samples of participants. They use both causative and descriptive elements of like themes to group events, sometimes referred to as ‘domain specific’ taxonomies (Kostopoulou 2006).

‘Multiaxial taxonomies’ capture additional elements of an event, such as harm levels, location, participants or preventability. One study has developed such a tool in a primary care setting in North America (Fernald, Pace et al. 2004; Westfall, Fernald et al. 2004), although its full details have not been published in the scientific literature. A further multiaxial taxonomy has been suggested as one that could allow comparison of safety events across disciplines, although no trial in a primary care setting has been described (Chang, Schyve et al. 2005).

There have also been some recent calls for classifications that address cognitive psychological processes (Zhang, Patel et al. 2004), with one developed for general practice (Kostopoulou 2006), which is yet to be tested. Finally, one taxonomy has been described that is based upon patients’ perceptions of harm in primary care,

although it has a limited application in terms of categorizing causes of events (Kuzel, Woolf et al. 2004).

The TAPS study estimated the incidence of general practitioner reported patient safety events in the community, using a method based upon a randomly selected representative sample of GPs (Makeham, Kidd et al. 2006). Major limitations mainly relating to the internal validity and practicality of existing tools warranted extensive taxonomy development. A major aim of the TAPS study was to develop a taxonomy that would be easily understood and practical for primary care clinicians to apply themselves. Further, we describe the first attempts to validate a taxonomy in terms of its inter-observer reproducibility with GPs (Makeham, Stromer et al. 2007).

The proposed TAPS taxonomy builds upon pilot work which has at its primary level a causative classification (Dovey, Meyers et al. 2002; Makeham, Dovey et al. 2002), adding sub-categories to this by grouping like themes, and then adding detail with descriptive categories in the style of a domain specific taxonomy. Application of the taxonomy to the TAPS data shows that the majority of reports contained a single patient safety event, and the majority of events reported by GPs related to the processes of providing health care rather than deficiencies in knowledge and skills of health professionals, as suggested in previous work with non-representative samples (Dovey, Meyers et al. 2002; Makeham, Dovey et al. 2002; Rubin, George et al. 2003; Elder, Vonder Meulen et al. 2004).

The reporting GPs demonstrated a clear understanding of the definition of error used (Makeham, Kidd et al. 2006), with less than 1% of reports being found by the group

of investigators to contain no safety event. In contrast to previous similar taxonomies (Dovey, Meyers et al. 2002; Elder and Dovey 2002; Makeham, Dovey et al. 2002), every second level theme contained a third level descriptor of ‘not otherwise specified’. This added descriptor allowed the proposed seven themes to adequately describe all reported safety events in the TAPS data, with no reports unable to be classified.

The largest proportion of events were classified as relating to ‘practice and health care systems’ at the theme level (21%, see section 4.9.4.1), consistent with American and UK studies (Dovey, Meyers et al. 2002; Rubin, George et al. 2003). Our category 1.1 is different from any used in previously described taxonomies as it contains elements of the larger health care system rather than just ‘administrative’ events. The 2002 pilot study found a similar proportion of ‘office administration’ events (20%) (Makeham, Dovey et al. 2002).

If both process and knowledge and skills event types are combined, the ‘medication’ groups represent the largest proportion at the theme level (31%, see sections 4.9.4.3 and 4.9.4.7), and this is similar to findings in earlier Australian studies (Britt, Miller et al. 1997; Bhasale, Miller et al. 1998). The separation of this group of events into the suggested types and descriptors provides a useful way to plan future preventive strategies such as targeted education for clinicians on specific medication groups versus systems changes that would reduce electronic prescription errors or dispensing mistakes.

A purpose of the study was to develop a tool that would be easily understood by primary care clinicians reporting safety events. The use of investigators with a clinical background in general practice was important to produce language that would be acceptable for self-coding. One other study has asked the reporting clinicians to code the events using a simple descriptive taxonomy (Rubin, George et al. 2003). However, as the study period was brief and the majority of reporters were reception staff, the authors noted that some event types may not have been captured.

There are no published studies with which a comparison of the results on reproducibility of the taxonomy can be made. The kappa statistic and proportions relating to inter-coder agreement showed a marked improvement in agreement from the pilot to the TAPS taxonomy at all levels of the code (see section 4.10). Some caution should be exercised in the interpretation of these results, as it is possible that some of this improvement (even though the GPs were independently coding), could have occurred through an unconscious learning of each others' styles at the taxonomy development meetings.

At the most detailed third level of the taxonomies, complete disagreement amongst the coders fell from over a quarter to less than ten per cent of cases (see section 4.10). In the cases where complete agreement was not reached, there was often difficulty in interpreting the reporting language used, or brevity of description provided in the report, requiring a degree of personal interpretation or assumption from the coding GPs. While further refinement of the taxonomy might lessen possible ambiguity, it is probable that a system where the reporting clinician actually codes the event would

reduce this type of error by eliminating a loss of detail in the process of describing the event and its cause to another clinician or analyst conducting the coding.

The taxonomy developed by the Applied Strategies for Improving Patient Safety (ASIPS) collaborative (Fernald, Pace et al. 2004; Westfall, Fernald et al. 2004) is a multiaxial model developed in a primary care setting, using trained analysts to classify reported events. It has not been published in the peer-reviewed literature in full, however it is able to be viewed online at www.cudfm.org/carenet/asips/taxonomy (accessed 27th July 2007). The TAPS electronic reporting system collects data of a similar nature to the additional axes and domains of ASIPS, including a harm scale, location check-box, event frequency scale, and details of patients such as age, gender and ethnicity (Makeham, Kidd et al. 2006). These elements are closed questions completed electronically by the reporter. They could be combined with reporters self-coding an event with the TAPS taxonomy to effectively produce a self-reported multiaxial taxonomy describing safety events.

An important limitation of the taxonomy event proportions is that they do not represent the underlying proportions of error types in the community, although the reporters were a representative sample. The study has not measured which event types may have been under-reported in comparison to others, and the incidence of reported error is likely to be an under-representation of the true incidence of error in a community setting despite efforts to encourage reporting (Makeham, Kidd et al. 2006).

The TAPS reports are a reflection of the experiences of GPs, and the taxonomy was created by GPs. As such, it may be limited in its application to other primary care groups. In other studies, a variety of clinicians or administrative staff have been involved in reporting events (Pace, Staton et al. 2003; Rubin, George et al. 2003; Wilf-Miron, Lewenhoff et al. 2003; Fernald, Pace et al. 2004; Westfall, Fernald et al. 2004; Shaw, Drever et al. 2005; Kostopoulou 2006; Williams and Osborn 2006). It may be important to explore language differences that may exist.

The TAPS reports and taxonomy may not have captured all error types that could be reported by a more diverse group. One other general practice taxonomy has recently been shown to be acceptable to opticians reporting safety events (Steele, Rubin et al. 2006). The TAPS taxonomy may similarly have potential uses to other disciplines in a community setting.

5.5 The measurement of patient harm in reported errors

Around one quarter of the errors reported in the TAPS study were associated with patients being harmed, as described in section 4.13. An analysis of the event types in harm positive reports found that reports containing events related to processes of health care were associated less with harm than those containing events related to the knowledge and skills of health professionals.

The patient related factors that were analysed found that in errors associated with patient harm, the patients were on average older than patients in reports where no harm was known to have occurred (58 years versus 50 years respectively, $p = 0.0076$).

There was no statistically significant difference found between these groups with respect to gender or ethnicity, including people from Non-English speaking backgrounds or Aboriginal and Torres Strait Islander (ATSI) people, although harm in association with errors involving the ATSI group was approaching statistical significance, and a larger number of results may in fact have found that this was a significant factor (see section 4.13.6).

Also related to harm, patient death was reported in 8 of 415 errors reported in the TAPS study (2%), and more often involved events relating to the knowledge and skills of health professionals (type 2) than events relating to the processes of health care (type 1) in comparison to reports not involving a known patient death.

There is very little research in the general practice or community setting that has been published in relation to the measurement of patient harm in association with reported errors. The critical incident study in Australia undertaken between October 1993 and June 1995 (see section 2.8.2) collected incidents of potential or actual harm reported by a non random sample of general practitioners (Bhasale, Miller et al. 1998). The questionnaire asked for structured responses to questions related to the potential for harm, immediate consequences and predicted long-term outcomes. The study found that 27% of reported incidents had the potential for severe harm, although no long term harm was predicted for 66% of incidents (Bhasale, Miller et al. 1998). In publications relating to this study (Britt, Miller et al. 1997; Bhasale 1998; Bhasale, Miller et al. 1998), the figure for the reports where actual harm occurred versus did not occur is not presented. Harm was not defined, although the 1 to 5 scale on the

form had 1 marked as 'mild' and 5 marked as 'severe' (Bhasale 1998), similar to that used in the TAPS study.

The TAPS study results are not easily comparable to the critical incident study (Britt, Miller et al. 1997; Bhasale 1998; Bhasale, Miller et al. 1998), as the harm question was framed quite differently. In the TAPS study, the one quarter of errors reported as harm positive was indicative of actual harm rather than potential harm. All reports were intended to have had the potential for harm based on the definition of error chosen, although this was not tested specifically with a closed question.

A similar harm result (22% of reports involved patient harm) was found in a study based in an academic medical centre in New York City in 2004 (Tuttle, Holloway et al. 2004). The setting and participants were quite different from TAPS, however, as the role of the physicians differed somewhat from those of the Australian GPs in TAPS, and reports were made by a variety of staff at the centre. Most of the reports were made by nursing staff (73%) rather than the physicians (2%) (Tuttle, Holloway et al. 2004). The study was conducted using a voluntary internal confidential electronic reporting system rather than an anonymous system.

Looking at the proportion of reports where death had occurred, the critical incident study (Britt, Miller et al. 1997; Bhasale 1998; Bhasale, Miller et al. 1998) found that 38 deaths were reported amongst 805 incidents over roughly a 2 year period, which gives a higher proportion to that found in TAPS. However, this was not a collection of reports from a single group of participants for the entire study duration – it was a non random volunteer group of 324 GPs who entered and left the study over some

point during the reporting period between October 1993 and June 1995. A valid comparison to the proportion of deaths reported in the TAPS study is not possible.

Some research has been published looking at cases of deaths in community settings and the association with errors as a cause (Berlin, Spencer et al. 1992; Holden, O'Donnell et al. 1998; Kristoffersen 2000). The studies that audited death found a range in the proportion that contained critical incidents, with a 1992 British study of 8 cases finding critical incidents in all (Berlin, Spencer et al. 1992). A Norwegian study published in 1998 followed a defined population and the deaths arising over a twelve month period, and looked at cases that had had a visit with an after-hours primary care physician in the preceding four weeks. It was found that the physicians may have misinterpreted events in 5% of cases (Kristoffersen 2000). It is not possible to draw any comparisons with these types of results as the overall number of deaths that may have occurred amongst patients of TAPS participants during the study period is not readily determined.

Beyond the community setting, studies relating to harm and death as a result of error may be found in the hospital setting. The Quality in Australian Healthcare study (QAHCS) reviewed over 14,000 admissions to 28 hospitals in NSW and South Australia in 1992 (Wilson, Runciman et al. 1995). It was based on the methods used in the landmark Harvard Medical Practice study (HMPS) conducted in the mid 1980s (Brennan, Leape et al. 1991; Leape, Brennan et al. 1991). The HMPS found that adverse events occurred in 3.7% of hospitalisations, and of these, 27.6% were due to negligence. The QAHCS found a much higher rate of adverse events, at 16.6% (Wilson, Runciman et al. 1995). Of these adverse events, 13.7% caused some form of

permanent disability and 4.9% resulted in death. The authors determined that 51% of the adverse events detected were preventable.

The hospital studies described above (QAHCS, HMPS) had very different definitions and methods to TAPS, as they looked at adverse events that harmed patients detected from medical record review, rather than examining cases of error with the potential for harm, regardless of actual outcome. They detected many cases of poor outcome for patients unrelated to systems or human failures and were essentially unpreventable, such as adverse drug reactions, which on the whole were not reported by TAPS participants, who tended to only report issues which they saw as preventable.

There are some major limitations to be considered when interpreting the harm findings presented in this thesis, and the methodology in future work should be adjusted in consideration of these points. No clear definition of “patient harm” or the term “serious” was given within the questionnaire, and some differences of interpretation by reporting GPs were likely to have occurred. Secondly, the harm rating scale had no indication of the meaning of the various points 1 to 5 that were intended to indicate severity of harm. The results of this question would be more consistent if a guide had been provided to assist participants in this respect. Thirdly, participants at the time of making reports may not always have been aware that a patient harm had resulted. Finally, it is possible that the participants, often reporting about errors that they had felt to be of their own doing, were reluctant to suggest that they had been responsible for causing harm to their patients, leading to an overall

under-reporting of the harm positive errors, and an underestimation of the severity of harm ratings.

Future research methods attempting to address this question may benefit from the use of a standard definition, such as that which now appears on the website of the Australian Commission on Safety and Quality in Healthcare at www.safetyandquality.org/internet/safety/publishing.nsf/Content/former-pubs-archive-definitions#e (accessed 27th July 2007). This defines harm as “Death, disease, injury, suffering, and/or disability experienced by a person”.

A suggestion for an improved rating scale of severity to accompany this which would be useful to improve the consistency of severity scoring could be as follows, and an example of each category could be provided to illustrate these levels further along with a definition of ‘seriousness’.

1 = Minor seriousness, reversible

2 = Moderate seriousness, reversible

3 = Extreme seriousness, reversible

4 = Irreversible harm

5 = Death or imminent death

5.6 Comments related to the preventability of reported errors

Interestingly in the TAPS study data, almost all cases reported had some aspect of preventability which was discussed by the participant (98%). This was an interesting result as the definition of error used did not specifically exclude errors where prevention would be difficult such as cases of adverse drug reactions or other errors

complying with the TAPS study definition: *'That was a threat to patient well-being and should not happen. I don't want it to happen again'*.

The three main types of error prevention reported by participants related to human factors of improving knowledge and skills, to changes in local systems factors around the event such as practice guidelines, and changes to the wider health care system.

The Australian general practice incident monitoring study conducted in the mid 1990s published 'preventability' at a much lower proportion of errors than this at 76% (Bhasale, Miller et al. 1998), and it is likely that the reasons for this difference lie in the definition used. This study had a different definition for error of *'An unintended event, no matter how seemingly trivial or commonplace, that could have harmed or did harm a patient'*. The addition of the phrase 'I don't want it to happen again' in the TAPS study definition may have introduced some sort of implication that the TAPS study was looking for issues that had some aspect of preventability about them, either due to the system or human elements involved in the cases.

An adverse drug reaction may represent an 'unpreventable' error, if due to the individual patient's physiology rather than an interaction. This reaction would be likely to happen again to the same patient with the same drug regardless of the actions of health care professionals or their systems of providing care, irrespective of the fact that the reporting physician wouldn't have wanted it to happen. It is possible that this changed the context somewhat of error reporting for the TAPS participants in comparison to the earlier Australian critical incident study.

Similarly, hospital studies examining ‘adverse events’ using medical record review such as the Quality in Australian Health Care study (QAHCS) have much lower proportions of cases that would be considered ‘preventable’, at only approximately 50% (Wilson, Runciman et al. 1995). The definition used for an index case was very different and included events such as adverse drug reactions. It should also be noted that the QAHCS had a 6 level gradation of preventability, and the figure of 50% relates to ‘high preventability’ cases, which included levels 4 (more likely preventable than not), 5 (strong evidence for preventability) and 6 (virtually certain evidence for preventability), and excluded levels 3 (preventability not likely, less than 50-50 but close call), 2 (slight to modest evidence for preventability) and 1 (virtually no evidence for preventability) (Wilson, Runciman et al. 1995).

To provide further insight into prevention methods relating to various event types in the community setting, future studies could have more rigorous data collection on the issue of preventability incorporated into the study design, allowing for more in depth post-hoc analysis.

5.7 The features of patients involved in reported errors

The finding of the TAPS study related to patient factors conclude that most reported errors involved patients (92%), that these patients were usually well know to the GPs reporting the errors, that they were on average 52 years old, slightly more often female (56%), of a non-English speaking background 16% of the time and an Aboriginal and Torres Strait Islander person 2% of the time (see section 4.11). Of these measures, patient age was the only factor found to have an association with harm as an outcome, with patients involved in reported errors associated with harm

being on average 8 years older than patients involved in reported errors that were not associated with harm (58 years versus 50 years respectively, $p = 0.0076$).

The number of individual patients seen by participants in the TAPS study was collected in order to address the question of the incidence of reported error per patient seen per year. Consent and a legal instrument for further details relating to the age, gender, and ethnicity for the specific group of patients seen by TAPS participants during the study period was not obtained. Although it was possible to conclude that participating GPs were a representative sample based on their age, gender and Medicare billings, the same comparisons cannot be made of the patient groups who attended the general practices of the TAPS participants. This means that although a comparison can be made to general Australian or NSW data on the average age and gender of patients or the average number of Aboriginal or Torres Strait Islander people attending GPs, it can't necessarily be assumed that the TAPS GPs overall saw a representative patient sample during the study period.

Attempting to compare patient factors such as the proportion of female patients or the average age of patients involved in errors to the background rates of these figures for patients visiting GPs in NSW is difficult. For example, although the average age of the patients in TAPS error reports is known, the study did not determine the average age of the other patients that participants saw during the study period, or the average age of patients seen by the source population of NSW GPs. It should be noted given the broad representation of GPs in the TAPS study, including major metropolitan as well as rural areas, that the patient populations are likely to be similar.

Looking at other studies of errors reported in community settings, Bhasale described some patient characteristics of those involved in the critical incident study in Australian general practice undertaken in the mid 1990s (Bhasale, Miller et al. 1998). In agreement with the TAPS study data, this study demonstrated a similar proportion of female patients (58% versus TAPS 56%, see section 4.11.4). The average ages and distributions were not published in the critical incident study, however the median age of patients was 50 years (range 0 – 98) compared with the TAPS median of 56 (range 0 – 104). Younger patients were less likely to be involved in incidents (Bhasale, Miller et al. 1998). Considering the different definition used in the Bhasale study (focusing on harm), this result may be similar to the TAPS finding that on average older patients were more often involved in harm positive events (see section 4.13.3).

Some detail of patient age and gender has been described in the literature in relation to reports of adverse drug reactions in general practice settings. An English study combining 48 national cohort studies of newly marketed drugs found that in general practice in England, suspected adverse drug reactions to newly marketed drugs are recorded more often in adults aged between 30 and 59 years of age, with females more commonly affected (56% female vs. 44% male) (Martin, Biswas et al. 1998). However, as previously discussed, these types of studies have a limited value in terms of comparison to the TAPS study data. Different definitions used in the TAPS study was likely to have resulted in an absence of reports relating to adverse drug events perceived as non-preventable (see section 5.6).

In future data collections using the TAPS methodology, a significant improvement in the ability to generalise findings could be obtained by collection of demographic and

patient factor data from the total cohort of patients seen by study participants. This would lead to more accurate comparisons between those patients involved in reported errors and the source population of patients from which they have come. This would require the consent of the participants and a further legal instrument from DOHA.

5.8 Future directions – error analysis and feedback as learning tools for GPs and the primary care sector

It has been suggested in recent years by the lead author of the landmark Quality in Australian Healthcare study (Wilson, Runciman et al. 1995) that despite an effort to improve the way patient safety issues are measured and analysed in Australia, there has really been very little progress made over the past decade (Wilson and Van Der Weyden 2005). A system which “captures the imagination of politicians, professionals and the public” was called for in 2005.

To date, only the National Patient Safety Agency of the National Health Service in the United Kingdom has an anonymous electronic error reporting system which is universally accessible to health care providers in both community and hospital settings, although almost no information on its use and acceptability to general practitioners is yet available (Shaw, Drever et al. 2005; Williams and Osborn 2006). Such a system however could be a way forward to improving our ability to use data on error in healthcare settings to learn from patient safety threats and improve Australian health systems in the community setting.

A broadly accepted and readily accessible error reporting system is more likely to diagnose and offer solutions to problems in healthcare than learning tools which are targeted at the level of the individual clinician and their learning needs. However, it should be noted that the TAPS study found that it was probably these types of mistakes (type 2 knowledge and skills errors), although less common, that were more often associated with patient harm (see section 4.13.2).

It has been proposed that the improvement of the safety culture or the acquirement of an improved degree of 'error wisdom' by some of those on the frontline could thwart some organisational accident sequences at the last minute (Reason 2004), and that vulnerable systems are more liable to adverse events (Reason, Carthey et al. 2001). Psychological factors such as inattention, distraction and forgetfulness are the last and often the least manageable aspects of the accident sequence (Reason 1995). Whereas individual unsafe acts are hard to predict and control, the organisational and contextual factors that give rise to them are present before the occurrence of an incident or accident. As such, they are prime candidates for treatment. Reason describes errors at the 'sharp end' as being symptomatic of both human fallibility and underlying organisational failings (Reason 1995). He proposes that fallibility, which can be moderated, but not eliminated, is here to stay, however organisational and local problems, in contrast, are both diagnosable and manageable.(Reason 2005)

In 2002, a leading Australian patient safety researcher, Professor Bill Runciman, described the evolution of the concepts and processes underpinning the Australian Patient Safety Foundation's systems over the previous 15 years (Runciman 2002).

Based on this, he describes the attributes of an ideal system for national patient safety surveillance. He proposes that such a system should have the following attributes:

- an independent organisation to coordinate patient safety surveillance
- agreed frameworks for patient safety and surveillance systems
- common, agreed standards and terminology
- a single, clinically useful classification for things that go wrong in health care
- a national repository for information covering all of health care from all available sources
- mechanisms for setting priorities at local, national and international levels
- a just system which caters for the rights of patients, society, and healthcare practitioners and facilities
- separate processes for accountability and "systems learnings"
- the right to anonymity and legal privilege for reporters
- systems for rapid feedback and evidence of action
- mechanisms for involving and informing all stakeholders.

Runciman proposes that there are powerful reasons for establishing national systems, for aligning terminology, tools and classification systems internationally, and for the rapid dissemination of successful strategies (Runciman 2002). He has recently published a comprehensive set of standard definitions which could be adopted in such a system (Runciman 2006).

Much work has been published in relation to the analysis of errors in the field of anaesthetics, and the Australian studies in this discipline by Runciman and others in the mid to late 1980s were amongst the earliest research on error in medicine around

the world (Runciman 1988a; Runciman 1988b; Runciman 1989). In 1993, it was published that although 70-80% of problems have some component of human error, its overall contribution to many problems may be small, and that studies of complex systems have revealed that up to 85% of problems are primarily due to deficiencies in the lay-out and processes of the system (Runciman, Webb et al. 1993).

Runciman has also highlighted that if interventions for adverse events are triggered only by serious outcomes, most problems would not be addressed, particularly the large number of 'mundane' problems which consume the majority of resources. He suggests that both serious and mundane problems should be addressed in attempts to improve patient safety in health care (Runciman, Edmonds et al. 2002).

The TAPS methodology and taxonomy has the potential for use as part of an anonymous national electronic reporting system, and offers guidance to policy makers in directing efforts to reduce patient safety threats in general practice, particularly at a systems level. Further application of the TAPS taxonomy may also aid professional bodies developing educational tools aimed at improving the knowledge and skills of providers in primary care.

A system such as TAPS could address many of the needs detailed by Runciman (Runciman 2002), but would require a substantial amount of further development and testing in health care settings other than general practice before any suggestion of its usefulness as a health care reporting system across all settings could be made.

6 Clinical lessons learnt from the TAPS study

The purpose of this section of the thesis is to broadly outline some of the major clinical lessons that have been learnt in the process of undertaking the TAPS study and analysing the error reports from GPs, and these are presented under the headings that relate to the level 2 themes of the TAPS taxonomy (see Appendix 10). Sections 6.1 to 6.5 relate to type 1 or ‘process’ errors, and sections 6.6 and 6.7 relate to type 2 or ‘knowledge and skills’ errors. Comparison is made to existing literature on events in the Australian general practice setting from the critical incident study of the mid-1990s (Bhasale, Miller et al. 1996b; Bhasale, Miller et al. 1996a; Bhasale, Miller et al. 1996c; Bhasale, Norton et al. 1996; Britt, Reid et al. 1996; Reid, Britt et al. 1996b; Reid, Britt et al. 1996a; Reid, Miller et al. 1996; Britt, Miller et al. 1997; Bhasale 1998; Bhasale, Miller et al. 1998) (as described in section 2.8.2).

6.1 Lessons from errors in practice and health care systems

The largest proportion of problems in this theme arose in association with patient record and filing system errors, closely followed by recall system errors. Some of the important clinical lessons relating to this theme are:

- Clinicians should be wary of the vigilance with which patient details are recorded in their systems. An absence of contact phone numbers or incorrect address details can lead to further problems, especially when investigation results requiring follow-up require the clinician to contact the patient.
- Simple paper and computer filing system errors that result in duplicate patient files can lead to serious problems when medications are being prescribed and the opportunity to screen for drug interactions is missed.

- An absence of establishing consistent recall systems can lead to serious harm for patients when an opportunity to follow up a previously abnormal examination or investigation finding is missed.

The critical incident study of the mid-1990s found that administrative inadequacies contributed to around 9% of incidents (Bhasale, Miller et al. 1998). The study described problems with incorrect patient record use, particularly in reference to errors in ordering and labelling specimens and request forms (Bhasale, Norton et al. 1996), which are further discussed below in section 6.2. Also described were problems with failing to have adequate recall systems in place. Examples cited included a failure to recall patients with serious abnormalities in pathology results, such as PAP smears (Bhasale, Miller et al. 1996b), and a failure to recall a patient requiring a follow-up examination of a breast abnormality (Reid, Miller et al. 1996).

6.2 *Lessons relating to investigation errors*

The main clinical lesson that arose in this group was related to the management of investigation reports:

- Vigilance in the practice system of checking and acting on investigation results is required to avoid serious harms to patients related to missing abnormal test results. This occurred in association with investigation reports being filed before the GP had seen them, reports being seen by the GP who missed an abnormal result (for example on a second page of a report), and abnormal results being noted by the GP initially but no system for follow-up was instigated and so patients went untreated.

The critical incident study identified four stages where incidents relating to tests and investigations were commonly found to have occurred. These were in arranging the test, in the testing process, in the communication of the results to GPs, and in the follow up of results with the patient (Bhasale, Norton et al. 1996). The TAPS taxonomy level three descriptors within the 1.2 category of investigation process errors were created along similar principles to these (see section 4.9.4.2).

In addition, the critical incident study highlighted two areas that required particular attention in relation to the management of test results, and these were very similar to the clinical lessons described in this theme of the TAPS study. These areas were how GPs are informed of the results, and the mechanism for informing patients of their test results and follow-up needs (Bhasale, Norton et al. 1996). It was found that over half of the incidents associated with investigations could probably have been prevented through more efficient systems for maintaining and passing on test results, and recalling patients for follow-up (Bhasale, Norton et al. 1996).

6.3 Lessons relating to process medication errors

A large number of the errors that were seen in this group related to medication dispensing errors, followed by electronic prescription writing errors. The significant clinical lessons were:

- Vigilance in the pharmacy in checking that the correct medication and strength is being dispensed to the patient is important in avoiding serious patient harms such as overdose.

- GPs using electronic script writing packages should be particularly wary of clicking on the wrong medication or strength of medication when choices are offered in ‘drop down’ menus.

The critical incident study was conducted prior to the widespread use of computers for medication prescribing that now exists in Australia. However it found that many errors, including prescription errors, were a result of ‘slips’ that related to GPs being tired, stressed or running late (Britt, Reid et al. 1996). Prescription errors were often a result of poor legibility or similarity in the names of drugs being prescribed.

Preventive strategies included greater vigilance in checking a written prescription, and suggestions to ‘adopt a computerised prescribing system which incorporates contraindication and interaction flags’ (Britt, Reid et al. 1996).

The widespread uptake of computerised script packages over the past 10 years is likely to have greatly influenced the number of these types of medication process errors in the Australian community setting. The TAPS study shows that systems that protect GPs from being ‘tired, stressed or running late’ still require attention as slips are still occurring in relation to prescribing process errors, despite computerisation.

6.4 Lessons relating to non-medication treatment errors

The TAPS study picked up a variety of general errors in relation to the taxonomy themes, however some examples of such as the one presented here were very specific.

The main clinical lesson from this group was highlighted in a letter to the MJA in 2004 (Makeham, Kidd et al. 2004), relating to the reconstitution of vaccines when active ingredient and diluent are presented in separate packaging:

- Health departments and drug companies should aim to present vaccines that require reconstitution in packaging that puts the vaccine and its diluent in the same box, to avoid the accidental injection of the diluent without the active component mixed in, as occurred with the Menjugate ten vial packs. GPs should maintain vigilance regarding vaccines that require reconstitution.

A report in the literature of an immunisation process error also exists from the critical incident study, in which a GP gave a child triple antigen instead of MMR due to a lack of carefully checking the label on the vaccine (Reid, Britt et al. 1996a). The contributing factors identified were not specific to an immunisation error. These included that the GP was 'stressed and running late', there was an older disruptive sibling present, no medication record was available, distractions and interruptions occurred during the consultation, and there was no protocol followed on administering a parenteral drug (Reid, Britt et al. 1996a).

6.5 *Lessons relating to communication errors*

Communication was an important aspect in many errors, and this category carried some important clinical lessons, particularly as the majority of problems in this theme occurred at the community-hospital interface.

- Hospital emergency department medical officers and ward medical officers should be as clear as possible in their discharge communications with GPs, as an absence of information on these resulted in some serious patient harm and a patient death reported in the TAPS study.

- Patient education regarding their hospital treatments and medications is an area of risk and should be improved, as patients on occasion had a poor understanding of new medication that had been commenced, and were reported to have taken double doses of medications on discharge from hospital as they had not been educated regarding brand versus generic names of drugs.

The critical incident study also highlighted communication problems between hospital and GP, noting that clinical information about the outcomes of hospital referrals or admissions, the expected role of the GP in post-discharge care, specialist's recommendations for management and results of tests or investigations was often not communicated, or too late to be of use (Bhasale, Miller et al. 1998). Preventive strategies were suggested that included improving hospital-GP communication systems, having individual GPs meet with hospital staff and communicating their needs, involving the patients in the process of contacting the GP, and generally improving relationships with hospitals through divisions of general practice or other groups (Bhasale, Miller et al. 1996a).

6.6 Lessons relating to errors in diagnosis

The main clinical lesson relating to diagnostic errors that were reported in the TAPS study was for clinicians to be vigilant in their application of clinical skills, particularly in the assessment of complex patients on home visits and in nursing home settings:

- Diagnostic error was often a result of an absence of adequately taking a history or examining a patient, and therefore failing to organise an appropriate investigation or treatment. Particular care should be taken to avoid attempting

to manage complex patients with inadequate time allowed, either as ‘fit-ins’ in the clinic, or in a rushed home visit or nursing home visit.

The critical incident study found that diagnostic incidents mainly occurred because of errors in judgement, particularly in the formation and evaluation of diagnostic hypotheses (Bhasale 1998). The most frequent contributing factors nominated by GPs in these cases related to errors in clinical judgement such as failing to recognise significant symptoms and signs, and poor communication. The inappropriate rejection of a correct hypothesis due to insufficient or incorrect evidence is suggested by the author as an important type of diagnostic error (Bhasale 1998). Similarly, the TAPS study clinical lesson in this theme related to an absence of obtaining adequate clinical information.

6.7 Lessons relating to errors in managing patient care

The majority of errors that occurred in this theme were related to the management of medication, particularly Warfarin errors. The important clinical lessons here are:

- Greater care should be taken in appropriately educating patients who are commenced on Warfarin, who were often unaware of the vigilance required in monitoring their medication.
- Clinicians should be vigilant regarding their duty of care to patients that they are managing on Warfarin, and institute handover and recall systems so that there is not a failure to check anticoagulation levels when required, particularly on weekends and when they are taking a leave of absence from their practice. This is to avoid the situation of over-anticoagulation leading to a patient death, as was reported in the TAPS study.

Warfarin prescribing was also clearly highlighted as an important area for improvement by the critical incident study (Bhasale, Miller et al. 1996c).

Contributing to the errors were consultations occurring at a time where it was difficult to obtain information (such as a weekend), missing information, poor communication, a lack of education of the patient and patient misunderstandings. Suggested preventive strategies included better patient education, improved communication both doctor-patient and doctor-doctor, and general management systems such as patients carrying a card identifying the lab responsible for their INR results (Bhasale, Miller et al. 1996c).

7 Recommendations for future research

Relatively little research into error in the community setting has occurred to date, and it is well recognised that much more is required to address a range of research questions in many different areas (Hammons, Piland et al. 2003). The purpose of this section of the thesis is to outline future research strategies that could address different types of research questions.

Four main strategies for further research, using methodologies that would be practical in a primary care setting, could address many of the outstanding research questions associated with the measurement of threats to patient safety in such settings. The methods proposed vary depending on the research questions being addressed:

1. Prospectively collected safety event data using simple descriptive taxonomies (large scale collections, national where appropriate) that clinicians, staff and patients could access in secure setting could appropriately address:
 - Questions relating to quantification of reported event types
 - Questions relating to primary care safety policy, observing frequencies of reported event types or harm levels pre and post-implementation
 - Questions relating to demographics of patients who are more vulnerable to certain types of reported safety events
 - Questions relating to communication problems at the community care and hospital interface
 - A need for the improvement of the safety culture in primary care, normalizing the reporting and discussion of safety events.

- A need for the development of self-directed educational tools relating to primary care safety practices, that could be linked and incorporate feedback from large scale safety event monitoring systems
2. Methods of in-depth analysis of safety events and multi-faceted, more detailed taxonomies incorporating event types with cognitive theories of causation and harm scores (for example short-term collections with detailed analysis of reported events, including methods such as external reviewers analysing events, focus groups, and interviews with reporters) could appropriately address:
- Questions relating to causation of patient safety events
 - Questions relating to contributing factors to safety event occurrence
 - Questions relating to preventive strategies to combat safety events
 - Questions relating to detailed reviews of specific event types (such as a study concentrating on factors associated with diagnostic failures or medication management mistakes)
3. Development of sophisticated electronic web-based safety event collection systems could address many requirements of both large scale safety event collections and detailed safety event analyses. With such a system controlled for example by a government or national safety organization, various studies, detailed analysis systems examining specific event types, feedback to clinicians, educational tools and a national reporting system could be housed and monitored simultaneously.

4. There is a need to develop methods that allow patients a voice in working the patient safety agenda in community settings. To date patients' views have been heard only through small-scale qualitative studies or in the analysis of complaints and risk management systems. An early challenge to address is to incorporate patients' perspectives on patient safety using valid methods that are devoid of the medico-legal threats to clinicians such as those associated with malpractice databases and complaints registers. Involving patients in this type of research is likely to result in measures of patient safety that are different from the current metrics, and which are all focused on the provider perspective.

It may be reasonably anticipated that factors influencing the nature of future research efforts will include:

- Time and financial cost levels associated with study types, with large scale collections requiring national infrastructure and support from governments or large regulatory agencies, and detailed analyses requiring the time commitment of primary care professionals plus direct research costs associated with data analysis.
- Access of primary health care professionals or patients to tools such as internet-based collection sites where security and anonymity could be maintained.
- The varying levels of involvement in research of this nature in different primary health care communities, some having had more exposure to efforts designed to improve the safety culture. These latter groups would be better placed to begin implementation of national collecting systems.

- Priorities with respect to need in primary care: safety event studies aimed at both detailed causation and broad event type quantification are required, and different areas will vary with respect to the main needs of professional groups, communities, regulatory organizations and governments.

In order to improve our ability to measure patient safety events in community settings, there is a great need to address the rigour with which research is designed in order to be able to generalise its findings, and for researchers to consider methods that will improve our ability to assess the internal validity of the taxonomies or other measurements being proposed. Much useful work has been done, however the study of safety in community settings is still in its infancy.

Appendix 1: Summary of relevant literature and key organisations

This appendix lists the findings identified by the search strategy previously outlined in table 2.1. These are broken down into groups relating to general safety event reporting, specific types of safety event reporting (such as medication events), and key organizations involved in safety research in community settings. These lists of related papers and organisations would be of use in directing readers to the relevant body of literature on the various sub-categories of patient safety events that are provided as headings throughout this appendix.

Literature on general patient safety events in community settings

a) Studies reporting or measuring patient safety

1. Patient safety events reported in general practice: A taxonomy. (Makeham, Stromer et al. 2007)
2. The Threats to Australian Patient Safety (TAPS) study: incidence of reported errors in general practice (Makeham, Kidd et al. 2006)
3. The development of the National Reporting and Learning System in England and Wales, 2001-2005 (Williams and Osborn 2006)
4. From cognition to the system: developing a multilevel taxonomy of patient safety in general practice (Kostopoulou 2006)
5. Learning from different lenses: Reports of medical errors in primary care by clinicians, staff, and patients. A project of the American Academy of Family Physicians National Research Network. (Phillips, Dovey et al. 2006)
6. Error classification in community optometric practice - a pilot project (Steele, Rubin et al. 2006)
7. Adverse events and near miss reporting in the NHS (Shaw, Drever et al. 2005)
8. Computer visualisation of patient safety in primary care: a systems approach adapted from management science and engineering (Singh, Singh et al. 2005)
9. [Preliminary results of an anonymous internet-based reporting system for critical incidents in ambulatory primary care] (in German) (Brun 2005)
10. Avoiding and fixing medical errors in general practice: prevention strategies reported in the Linnaeus Collaboration's Primary Care International Study of Medical Errors (Tilyard, Dovey et al. 2005)
11. Medical errors in primary care: results of an international study of family practice (Rosser, Dovey et al. 2005)
12. Event reporting to a primary care patient safety reporting system: a report from the ASIPS collaborative.[see comment](Fernald, Pace et al. 2004)
13. The identification of medical errors by family physicians during outpatient visits (Elder, Vonder Meulen et al. 2004)
14. Patient reports of preventable problems and harms in primary health care.[see comment] (Kuzel, Woolf et al. 2004)
15. Learning from malpractice claims about negligent, adverse events in primary care in the United States (Phillips, Bartholomew et al. 2004)
16. A string of mistakes: the importance of cascade analysis in describing, counting, and preventing medical errors.[see comment] (Woolf, Kuzel et al. 2004)
17. [Medical errors and iatrogenic injury--results of 173 Schlichtungsstellen proceedings in general practice] (Scheppokat 2004)

18. Errors in general practice: development of an error classification and pilot study of a method for detecting errors.[see comment] (Rubin, George et al. 2003)
19. Database design to ensure anonymous study of medical errors: a report from the ASIPS Collaborative (Pace, Staton et al. 2003)
20. Family physicians' solutions to common medical errors(Dovey, Phillips et al. 2003a)
21. Consequences of medical errors observed by family physicians (Dovey, Phillips et al. 2003b)
22. Types of medical errors commonly reported by family physicians (Dovey, Phillips et al. 2003c)
23. From aviation to medicine: applying concepts of aviation safety to risk management in ambulatory care (Wilf-Miron, Lewenhoff et al. 2003)
24. Errors in general practice: Results of the international PCISME-study in Germany (Beyer, Dovey et al. 2003)
25. A preliminary taxonomy of medical errors in family practice (Dovey, Meyers et al. 2002)
26. An international taxonomy for errors in general practice: a pilot study.[see comment] (Makeham, Dovey et al. 2002)
27. Analysis of 1263 deaths in four general practices (Holden, O'Donnell et al. 1998)
28. The wrong diagnosis: identifying causes of potentially adverse events in general practice using incident monitoring (Bhasale 1998)
29. Analysing potential harm in Australian general practice: an incident-monitoring study.[see comment] (Bhasale, Miller et al. 1998)
30. Collecting data on potentially harmful events: a method for monitoring incidents in general practice (Britt, Miller et al. 1997)
31. Adverse events in primary care identified from a risk-management database.[see comment] (Fischer, Fetters et al. 1997)
32. From novice to proficient general practitioner: a critical incident study (Sim, Kamien et al. 1996)
33. Perceived causes of family physicians' errors.[see comment] (Ely, Levinson et al. 1995)
34. A critical incident study of general practice trainees in their basic general practice term (Diamond, Kamien et al. 1995)

b) Studies on the attitudes of health care professionals to safety event reporting

1. General practitioners' attitudes toward reporting and learning from adverse events: results from a survey (Mikkelsen, Sokolowski et al. 2006)
2. Effectiveness of a graduate medical education program for improving medical event reporting attitude and behavior (Coyle, Mercer et al. 2005)

3. [Possibilities for quality improvement in general practice by learning from adverse events] (Mikkelsen, Rubak et al. 2004)
4. Design elements for a primary care medical error reporting system (Beasley, Escoto et al. 2004)
5. The emotional impact of mistakes on family physicians.[see comment] (Newman 1996)
6. Assessing the quality of data entry in a computerized medical records system (Dambro and Weiss 1988)

c) Review articles and opinion pieces on patient safety events

1. [Incident reporting on its way to general practice] (Moller 2006)
2. Mandatory state-based error-reporting systems: current and future prospects.[see comment] (Wood and Nash 2005)
3. The frequency and nature of medical error in primary care: understanding the diversity across studies (Sandars and Esmail 2003)
4. Ambulatory patient safety. What we know and need to know (Hammons, Piland et al. 2003)
5. Error and safety in primary care: no clear boundaries (Jacobson, Elwyn et al. 2003)
6. Making the case for a qualitative study of medical errors in primary care (Kuzel, Woolf et al. 2003)
7. Classification of medical errors and preventable adverse events in primary care: a synthesis of the literature.[erratum appears in J Fam Pract. 2002 Dec;51(12):1079.] (Elder and Dovey 2002)
8. Promoting patient safety in primary care. Practices should set up their own critical incident reporting.[comment] (Ruffles 2002)
9. Enhancing public safety in primary care (Wilson and Sheikh 2002)
10. Promoting patient safety in primary care.[see comment] (Wilson, Pringle et al. 2001)
11. Setting up a database of medical error in general practice: conceptual and methodological considerations (Sheikh and Hurwitz 2001)
12. Evidence on interventions to reduce medical errors: an overview and recommendations for future research.[see comment] (Ioannidis and Lau 2001)
13. Patient safety: a call to action: a consensus statement from the National Quality Forum (Kizer 2001)
14. Analysing potential harm in Australian general practice: an incident-monitoring study.[comment] (Flaherty 1999)
15. An analysis of Australian adverse drug events (Malpass, Helps et al. 1999)

Literature on specific types of patient safety events in community settings

a) Medication related patient safety events in community settings

i) Reporting or measuring medication events

1. Adverse drug events in general practice patients in Australia.[see comment] (Miller, Britt et al. 2006)
2. Risk of adverse drug events by patient destination after hospital discharge (Triller, Clause et al. 2005)
3. Evaluation of laboratory monitoring alerts within a computerized physician order entry system for medication orders.[see comment] (Palen, Raebel et al. 2006)
4. Incidence and predictors of all and preventable adverse drug reactions in frail elderly persons after hospital stay (Hanlon, Pieper et al. 2006)
5. A distance-learning program in pharmacovigilance linked to educational credits is associated with improved reporting of suspected adverse drug reactions via the UK yellow card scheme (Bracchi, Houghton et al. 2005)
6. The potential of UK clinical databases in enhancing paediatric medication research (Wong and Murray 2005)
7. Prospective study of the incidence, nature and causes of dispensing errors in community pharmacies (Ashcroft, Quinlan et al. 2005)
8. Clinical relevance of automated drug alerts from the perspective of medical providers (Spina, Glassman et al. 2005)
9. [Reporting the discharge medication in the discharge letter. An explorative survey of family doctors] (Roth-Isigkeit and Harder 2005)
10. Patient-reported medication symptoms in primary care (Weingart, Gandhi et al. 2005)
11. Neuropsychiatric reactions to drugs: an analysis of spontaneous reports from general practitioners in Italy (Galatti, Giustini et al. 2005)
12. Pharmacovigilance in the 21st century: new systematic tools for an old problem.[comment] (Szarfman, Tønning et al. 2004)
13. [Databases as a source for monitoring systems of drug safety (Pigeot and Ahrens 2004)]
14. The involvement of nurses in reporting suspected adverse drug reactions: experience with the meningococcal vaccination scheme (Ranganathan, Houghton et al. 2003)
15. A feasibility study for recording of dispensing errors and near misses' in four UK primary care pharmacies (Chua, Wong et al. 2003)
16. Investigation into the reasons for preventable drug related admissions to a medical admissions unit: observational study (Howard, Avery et al. 2003)

17. Evaluating a medical error taxonomy (relates to NCC MERP taxonomy) (Brixey, Johnson et al. 2002)
18. Automated signal generation in prescription-event monitoring (Heeley, Wilton et al. 2002)
19. Improving adverse-drug-reaction reporting in ambulatory care clinics at a Veterans Affairs hospital (Aspinall, Whittle et al. 2002)
20. Postdischarge adverse drug reactions in primary care originating from hospital care in France: a nationwide prospective study (Letrilliart, Hanslik et al. 2001)
21. Using computerized data to identify adverse drug events in outpatients (Honigman, Lee et al. 2001)
22. Consultations owing to adverse drug reactions in a single practice.[see comment] (Millar 2001)
23. Hospitals do not inform GPs about medication that should be monitored (Corry, Bonner et al. 2000)
24. Adverse drug reactions and polypharmacy in the elderly in general practice (Veehof, Stewart et al. 1999)
25. Adverse drug reaction reporting by general medical practitioners and retail pharmacists in Harare--a pilot study (Ball and Tisocki 1998)
26. Under-reporting of adverse drug reactions. Estimate based on a spontaneous reporting scheme and a sentinel system (Alvarez-Requejo, Carvajal et al. 1998)
27. Under-reporting of adverse drug reactions in general practice (Moride, Haramburu et al. 1997)
28. [Drug induced fatal anaphylactic shock in Denmark 1968-1990] (Lenler-Petersen, Hansen et al. 1996)
29. Reporting adverse drug reactions in an ambulatory care setting (Finn and Carlstedt 1995)
30. Drug-related fatal anaphylactic shock in Denmark 1968-1990. A study based on notifications to the Committee on Adverse Drug Reactions (Lenler-Petersen, Hansen et al. 1995)
31. [Reporting of adverse drug reactions by primary care physicians] (Bravo Toledo and Campos Asensio 1995)
32. [Approximation to the detection of drug adverse reactions among doctors at the primary health care level] (Valero Martin, Jimenez Luque et al. 1993)

ii) Medication events from the perspective of patients

1. Patient-reported medication symptoms in primary care (Weingart, Gandhi et al. 2005)
2. Improving adverse-drug-reaction reporting in ambulatory care clinics at a Veterans Affairs hospital (Aspinall, Whittle et al. 2002)
3. Patient reporting of potential adverse drug reactions: a methodological study (Jarernsiripornkul, Krska et al. 2002)

4. Patients' experiences of antihypertensive drugs in routine use: results of a Danish general practice survey (Borrild 1997)

iii) Attitudes of primary health care professionals to medication event

1. Physicians' decisions to override computerized drug alerts in primary care (Weingart, Toth et al. 2003)
2. Attitudes to reporting adverse drug reactions in northern Sweden (Backstrom, Mjorndal et al. 2000)
3. Communication regarding adverse drug reactions between secondary and primary care: a postal questionnaire survey of general practitioners (Green, Mottram et al. 1999)
4. [Adverse drug reactions and a program of voluntary notification: an opinion survey of primary care physicians] (Serrano Cozar, Esteban Calvo et al. 1997)
5. Attitudes to adverse drug reaction reporting in the Northern Region (Bateman, Sanders et al. 1992)

iv) Review Articles and Opinion Pieces on medication events

1. Off-label and unlicensed prescribing for newborns and children in different settings: a review of the literature and a consideration about drug safety (Cuzzolin, Atzei et al. 2006)
2. Adverse drug events: counting is not enough, action is needed.[comment] (Roughead and Lexchin 2006)
3. Adverse drug events: counting is not enough, action is needed.[comment] (Miller, Britt et al. 2006)
4. JCAHO views medication reconciliation as adverse-event prevention (Thompson 1530)
5. Strategies to reduce medication errors in ambulatory practice (Adubofour, Keenan et al. 2004)
6. The general practice research database: role in pharmacovigilance (Wood and Martinez 2004)
7. Medication errors in family practice, in hospitals and after discharge from the hospital: an ethical analysis (Clark)
8. The perils of prescribing (Parsons 2002)
9. Adverse drug reactions.[comment] (Anton and Cox 2001)
10. An update of adverse drug reactions of relevance to general dental practice (Flint, O'Sullivan et al. 2000)
11. Active monitoring of adverse drug reactions in children. (Menniti-Ippolito, Raschetti et al. 2000)
12. [Incidence and prevalence of adverse drug reactions] (Haramburu, Pouyanne et al. 2000)

13. Age and sex distribution of suspected adverse drug reactions to newly marketed drugs in general practice in England: analysis of 48 cohort studies (Martin, Biswas et al. 1998)
14. The UK General Practice Research Database.[see comment] (Walley and Mantgani 1997)
15. A database worth saving.[comment] (Jick 1997)
16. Drug companies should report side effects in terms of frequency.[see comment] (Bracchi 1996)
17. Medication errors. Automation holds promise of prevention (Bazzoli)
18. Post marketing surveillance versus clinical trials: which benefits the patient? (Lawson 1994)
19. [Underreporting of adverse reactions to drugs: is it due to primary care or hospital care?].[comment] (Tejedor, Sanchez del Viso et al. 1994)
20. [Adverse reactions to drugs reported by the primary care physicians of Andalusia. Analysis of underreporting].[see comment] (Torello Iserte, Castillo Ferrando et al. 1994)
21. [Quality of event data in detection of unwanted drug side-effects in general practice of established physicians] (Schadlich 1993)
22. Yellow card reporting (Kelleher and Carmichael 1993)
23. Drug utilization studies and drug monitoring in The Netherlands (Haaijer-Ruskamp and de Jong-van den Berg 1991)
24. Post marketing surveillance of adverse drug reactions in general practice. I: search for new methods (Inman 1981)

b) Radiological events

1. Radiology by non-radiologists: is report documentation adequate? (Weiner 2005)

c) Vaccine events

1. Vaccine adverse events: separating myth from reality (Kimmel 2002)

Key organizations researching patient safety events in community settings

a) International and national patient safety organizations and groups

1. WHO World Alliance for Patient Safety <http://www.who.int/patientsafety/en>

Launched in 2004, the WHO World Alliance for patient Safety stands as the main international advocate for patient safety research, including research in community settings.

2. **Agency for Healthcare Research and Quality, USA**

<http://psnet.ahrq.gov/index.aspx>

AHRQ is the lead government agency in the USA for research on patient safety, health care quality, costs, and outcomes. It supports the AHRQ Patient Safety Network (PSNet), a national web-based resource providing access to resources about patient safety, including patient safety in community settings.

3. **National Patient Safety Foundation** www.npsf.org

NPSF is a not-for-profit organization based in the USA that aims to improve patient safety by a number of mechanisms, including research funding. It has funded 26 research projects, including several with relevance to community settings.

4. **National Patient Safety Agency, UK** www.npsa.nhs.uk

NPSA coordinates the efforts of people involved in health care, and promotes learning from patient safety incidents occurring in the United Kingdom's National Health System (NHS). It is involved in collecting and analysing information on patient safety events from local NHS organizations, staff, patients and carers.

5. **Australian Patient Safety Foundation** <http://www.apsf.net.au>

APSF is an independent not-for-profit organisation providing leadership in the reduction of harm to patients in all health care environments, including community settings. The APSF provides a software tool, the Advanced Incident

Management System (AIMS). This captures safety event information from a variety of settings in a consistent way, to enable subsequent detailed analysis.

6. Australian Commission on Safety and Quality in Health Care

<http://www.safetyandquality.org>

This government-funded Commission has developed a national strategic framework to promote patient safety and associated work program to guide efforts in improving safety and quality across the healthcare system in Australia.

b) International and national professional and research organizations

1. American Academy of Family Physicians

This Family Physicians' professional organization is the host organization for the National Network of Family Physicians, which have been involved in several primary care research studies on patient safety topics (Dovey, Meyers et al. 2002; Makeham, Dovey et al. 2002; Beyer, Dovey et al. 2003; Dovey, Phillips et al. 2003a; Dovey, Phillips et al. 2003b; Dovey, Phillips et al. 2003c; Phillips, Bartholomew et al. 2004; Woolf, Kuzel et al. 2004; Rosser, Dovey et al. 2005; Tilyard, Dovey et al. 2005). Publisher of the journal *American Family Physician*, which has printed papers reviewing patient safety issues.

2. American Board of Family Practice

Family Physicians' professional organization. Publisher of the *Journal of the American Board of Family Medicine*, which has printed papers discussing patient safety in the community.

3. College of Family Physicians of Canada

Family Physicians' professional organization. Publisher of the *Canadian Family Physician*, which has printed papers discussing patient safety in the community.

4. College of Family Physicians Singapore

Family Physicians' professional organization. Has a web-searchable function that demonstrates that patient safety issues are addressed across a wide range of this College's activities.

5. EQuIP (European Working Party on Quality in Family Practice)

A European group comprising members who conduct and use research related to quality improvement in general practice/family medicine, including research related to patient safety in community settings.

6. International Primary Care Respiratory Group (IPCRG)

An international umbrella organisation for national primary care respiratory interest groups, IPCRG aims to undertake international research in community settings, including research related to patient safety.

7. Irish College of General Practitioners

General practitioners' professional organization. Confers an annual award sponsored by the Irish Society for Quality and Safety in Healthcare for quality improvements relating to improved patient safety.

8. North American Primary Care Research Group (NAPCRG)

NAPCRG is a multidisciplinary organization aiming to foster primary care research. Since 2001 it has had a Patient Safety Special Interest research group, comprising primary care researchers interested in patient safety research.

9. Royal Australian College of General Practitioners

General practitioners' professional organization. Publisher of the *Australian Family Physician*, which has printed papers discussing patient safety in the community. It has developed a broad range of resources focusing on improved patient safety including education modules and tools providing safety checklists,

and has been directly involved in published research on safety events in community settings (Makeham, Dovey et al. 2002; Makeham, Kidd et al. 2006).

10. Royal College of General Practitioners

General practitioners' professional organization. Publisher of the *British Journal of General Practice*, which has printed papers discussing patient safety in the community. The college has two research units but neither has reported conducting research directly related to patient safety.

11. Royal New Zealand College of General Practitioners

General practitioners' professional organization. Publisher of the *New Zealand Family Physician*, which has printed papers discussing patient safety in the community.

12. Society of Teachers of Family Medicine

Professional organization for teachers of family medicine based in USA. Publisher of the journal *Family Medicine*, which has printed papers discussing patient safety in the community. There are several reports and resources about patient safety in community settings posted on its website.

13. World Organization of National Colleges, Academies, and Academic

Associations of General Practitioners / Family Physicians (WONCA)

WONCA is an international academic and scientific society for general practitioners in member countries. The WONCA International Classification Committee (WICC) developed the International Classification of Primary Care (Lamberts, Meads et al. 1985) as a tool for describing primary care activity. In 2005 it considered incorporating a patient safety chapter into this tool but no progress has yet been made on this initiative.

c) University departments and professional groups that have conducted patient safety research in community settings identified in the literature

Most published research has been produced by researchers working in academic departments of general practice in universities. The following academic departments, schools, and centres have produced patient safety research relevant to this review:

1. Department of General Practice, University of Western Australia, Australia
2. Department of Family Practice, University of Iowa, USA
3. University of Rochester, NY, USA
4. University of Michigan, Ann Arbor, USA
5. Department of General Practice, University of Sydney, Australia.
6. The Robert Graham Center: Policy Studies in Family Practice/Primary Care, USA
7. Institute for Family Medicine, Kiel University, Germany.
8. Department of Family Medicine, Virginia Commonwealth University, USA
9. Department of General Practice, Dunedin School of Medicine, New Zealand
10. Department of Family Medicine, Queen's University, Canada
11. School of Primary Care, University of Manchester, UK
12. Department of General Practice, University of Nijmegen, Netherlands
13. Department of Family Medicine, University of Colorado, USA
14. Department of Risk Management, Maccabi Healthcare Services, Israel
15. Centre for Primary and Community Care, University of Sunderland, UK
16. Sunderland Teaching Primary Care Trust, Sunderland, UK
17. Department of Family Medicine, University of Cincinnati, USA
18. State University of New York at Buffalo, NY, USA
19. Department of Primary Care and General Practice, University of Birmingham, UK

Appendix 2: Information and Consent Form for GP Participants

This appendix contains the information and consent form that was provided to and signed by participating GPs prior to the commencement of the TAPS study data collection.

Consent Form and Information Sheet for Doctors

Study Title: Investigating Threats to Australian Patient Safety in General Practice.

You are invited to participate in this research study. You have been randomly selected from a list of all of the GPs in NSW. This study aims to take an in-depth look at aspects of errors recognized by Australian General Practitioners. There is no work to date which addresses the question of the frequencies of different types of errors recognized in General Practice either in Australia or elsewhere, and this study will attempt to answer this question.

This form will describe the purpose and nature of the study, its possible risks and benefits, and your rights as a participant in the study. Please take whatever time you need to discuss the study with your colleagues and friends. The decision to participate is yours.

Background and purpose of the study

In 2001, the Department of General Practice of The University of Sydney participated in an international pilot study, entitled *The Primary Care International Study of Medical Errors (PCISME)*. This descriptive study was coordinated by The Robert Graham Centre of the American Academy of Family Physicians. The results from six participating countries were used to create an international taxonomy of errors in General Practice, and the Australian results have been published (Makeham MAB, Dovey SM, County M, Kidd MR. An international taxonomy for errors in general practice: a pilot study. *Med J Aust.* 2002; 177: 68 – 72)

Building upon the preliminary findings of the *PCISME* pilot, this study aims to take a closer look at aspects of errors recognized by Australian General Practitioners. The targeting of preventable errors in General Practice is an important step towards improving patient care and reducing harm. There is no work to date which addresses the question of the frequencies of different types of errors recognized in General Practice either in Australia or elsewhere, and this study will attempt to answer this question.

In Australia, the vast majority of interactions between patients and health professionals occur in Primary Health Care, and a large proportion of these occur in General Practice. By more extensively studying errors occurring in General Practice, it will be possible to analyse factors that contribute to these mistakes, and advise health policy makers regarding system changes that could reduce their occurrence. We may then achieve improvements in patient safety and cost saving for the community, through the reduction of morbidities that require the use of further services in the health care sector.

Total number of participating doctors

80 General Practitioners from a random stratified sample from Rural, Remote, and Metropolitan areas will take part in this study.

General Plan of this study

The overall design of the study is a survey of 80 general practitioners that are actively engaged in clinical practice each within one of the above three categories. Error reports will be collected via a report form downloaded from and submitted to a secure web site. The Internet Service Provider hosting the site will make a copy of the error reports onto a CD Rom once per month, and these will be used in the Department of General Practice for data analysis by the Principal Investigator's and stored in a secure office. **Throughout all of the study's processes, appropriate safeguards will be taken to ensure confidentiality of patients and doctors.**

Study participants:

Study participants will be a systematic sample of 80 General Practitioners. We will enroll 40 GPs from RRAMA 1(Rural, Remote and Metropolitan Area Classification), 20 GPs from RRAMA 2 –3, and 20 GPs from RRAMA 4-7. The latter two groups will be proportionally stratified within these subgroups as per the 7 RRAMA categories.

Eligibility criteria

1. Practicing in general practice.
2. Usually provides direct patient care for the majority of their work time (at least 20 hours per week).
3. Usually will be absent from their clinical work setting for no more than six weeks out of the twelve months data collection period of the study.
4. Comfortable with use of computers and have access to a personal computer (pc)
5. Able to establish reliable internet access via an internet service provider (ISP).
6. Willing to participate in the study.

Who cannot participate?

This study is designed to report the observations of medical doctors whose main work activity is clinical practice. Others working in the practices of participating physicians will not be directly involved in primary data collection for this study, although we appreciate that their observations will be important for inclusion in other investigations. General Practitioners whose main work activity is teaching or research are not eligible to contribute to the study as participants.

Definition of “error”

For the purpose of this study an error will be defined as follows

Errors are events in your practice that make you conclude: *“that was a threat to patient well-being and should not happen. I don’t want it to happen again”*. Such an event affects or could affect the quality of the care you give your patients. Errors may be large or small, administrative or clinical, or actions taken or not taken. Errors may or may not have discernable effects. Errors in this study will be anything that you identify as something wrong, to be avoided in the future.

Study Procedure:

When we receive a signed consent form in the Department of General Practice, we will mail you a one page form asking 9 questions about yourself and your practice. No names or identifying codes are written on this form. We will ask you to send the form back to us.

Study participants will be given a password to access a highly secure website. They will be asked to anonymously report on all errors that they note in their daily practice over a 12 month time period. The website contains a structured questionnaire, piloted in 2001, which guides doctors through the details of the error. Participants will be required to maintain an internet connection and their own hardware.

Participants will choose a Personal Identification Number of up to 8 characters. Each report will be identified by this PIN, but there will be no way of connecting a GP to this number, which is for the purpose of determining how many reports are submitted on average per participant. High level security involving encryption of the data during transmission will be used, and has been designed in consultation with a network security engineer.

All reports will be anonymous and unable to be linked to a specific study participant. Participants will be asked not to include any information in their reports which could be linked to a specific person or location.

Because we will not know which error reports you have sent in, most contacts between the investigators and the doctors in this study will be with the whole group of participating doctors. A member of the research team will contact you about once per month to check whether you recall noticing any errors that you were too busy to report. No details of these will be required.

Participants will be asked to provide permission for the chief investigators, Dr Meredith Makeham and Professor Michael Kidd, to access the number of medicare services provided over the twelve months of the study. This information will not be released to any outside parties, and we will pool your number of services with all the other participants. We will then destroy any record of services you provided. We need this information to be able to calculate the frequency of errors that occurred over the group as a whole.

Length of the study for each participant

We ask you to report mistakes that occur in your practice each day for one year beginning October 1, 2003.

DATA to be collected

The following data will be collected.

1. (To be collected at enrolment by research co-ordinator)

Doctor and Practice data, recorded on paper forms:

- i. Age and Years in practice (excluding training)
- ii. Sex of doctor.
- iii. Number of half-days worked in clinical practice in a usual week.
- iv. Number of patients seen on a usual half-day of clinical work.
- v. Whether medical students, residents, or registrars are taught in the practice.
- vi. Number and full-time equivalent number of doctors practicing in the practice.
- vii. Number and full-time equivalent number of other people working in the practice.
- viii. Use of computers in the practice.
- ix. Practice setting – RRAMA classification.

2. Error reports, to be sent electronically

The questions on the error report form are as follows:

- a) Is the problem related to a specific patient (*yes/no*). If “No”, skip to c.
- b) If yes, How well do you know the patient? (*Likert scale*)
- c) Patient age and sex.
- d) Does patient belong to an ethnic minority group? (*yes/no*)
- e) Does patient have a complex health problem? (*yes/no*)
- f) Does patient have a chronic health problem? (*yes/no*)
- g) What happened? (*free text field*)
- h) What was the result? (*free text field*)
- i) What may have contributed to this error? (*free text field*)
- j) What could have prevented it? (*free text field*)
- k) Where did the error happen? (*Check boxes*)
- l) To your knowledge, was any patient harmed by this error? (*yes/no*)
- m) If yes, how would you rate the seriousness of this harm? (*Likert scale*)
- n) How often does this error occur in your practice? (*Likert scale*)
- o) Do you practice in a RRAMA 1, RRAMA 2-3, or RRAMA 4-7 location? (*Check boxes*)
- p) Other comments (*free text field*)

3. De-identified medicare data for each participating General Practitioner

The pooled number of consultations per RRAMA classifications will be used to analyse the frequencies of self-reported errors per grouping.

Possible risks of participating in the study

Benefits to patients

Patients of contributing doctors may benefit from having errors corrected that might normally not have been identified and remedied. In the longer term, we expect that patients will benefit from more often having threats to their safety dealt with before they can cause harm.

Benefits to doctors

Participating doctors will be offered an honorarium for their participation in the study, of \$200 (+ GST), to compensate them for supplying the hardware and supporting the internet access required for their participation in the study. RACGP Quality Assurance Audit Points may be granted for participation in this study, pending the outcomes of our application. The information generated by this study will be able to be used to target vocational teaching of general practice in Australia.

Benefits to health systems

Others may benefit in the future from the information we obtain from this study. It will provide information about the type of errors that occur and is expected to help identify strategies to avert threats to patient safety. Other benefits arising from this new knowledge from settings outside hospitals will help to ensure that impractical government regulations might be avoided. Greater protection of patient safety and cost savings to patients, doctors, and health systems might ultimately be expected due to averted errors, through improved knowledge.

Possible risks of participating in the study

Risks to patients

There are few increased risks to patients beyond the usual risks they take in obtaining medical care. There is a small increased chance of breach of confidentiality if reporting doctors inadvertently include in their reports data that could identify patients. Study procedures and reporting tools minimise this risk.

No one (including PIs) will be able to determine which doctors submitted individual error reports, so there will be no possibility of intervention to ensure the safety of individual patients. We will however know the names of all doctors participating and can advise participants as a group of special threats and their remedies.

Care will be taken to ensure that no description that could potentially identify individual patients will be reported in any publication.

Reporting errors in this study does not relieve reporting doctors of their medical and legal obligations to ensure patient safety according to the social, professional, and legal standards in existence.

Risks to doctors

In theory, we recognize that there is increased potential for doctors to be exposed to medical legal risks. To reduce this risk, we have designed the research process to ensure that the reports of errors will not be able to be linked to any data that could

identify the contributors of these reports (please see section on Data Security). We believe our security and anonymity measures make the risk of linking a GP to an error report and subsequent litigation practically impossible.

It is possible that this research will attract criticism if the findings are very different from existing knowledge. Study participants may feel that this implies criticism of their practice and/or their observations.

Risks to health systems

It is likely that aspects of our health system will be identified as being ineffective or dangerous, and so risk of having their weaknesses exposed. The results of this study are likely to suggest changes to the status quo in the systems currently operating.

No one (including the PIs) will be able to determine which doctors submitted individual error reports, so there will be no possibility of intervention to ensure the safety of individual patients. Care will be taken to ensure that no description that could potentially identify individual patients will be reported in any publication.

Data Collection

Data security measures mean that the error reports stored on the secure server can only physically be accessed from this single location, which will be the headquarters of the Australian Internet Service Provider who is contracted to host the website. The Australian ISP hosting the website will make a copy of the anonymous error reports onto CD Rom once per month, and these will be used in the Department of General Practice for data analysis by the Principal Investigators and stored in a secure office.

Confidentiality of the data collected during the study

No patient names will ever be used in this study. Other possible identifiers include only approximate age and sex. Doctors will be specifically reminded to avoid including identifiers in each error report and each report will be scanned by the country PI and the international PI for identifiers, which will be edited from the record, if they occur.

Whenever data from this study are published, participating doctors' names will not be used without their consent. Publications of primary care research usually acknowledge contributing doctors. If doctors prefer not to be listed as a contributor, this preference will be respected.

The research data are recollections and observations of General Practitioners. At no time will medical records be retrospectively screened for indications of errors in the process of care.

In order to determine the frequencies of self-reported errors, it is necessary to collect the total number of patient encounters seen by the participants over the study period.

Consent will be obtained prior to study participation to access the de-identified medicare data of each doctor for this purpose. This data will be pooled according to RRAMA classification prior to analysis. There will be no records kept linking an individual GP to his or her medicare data, and no analysis or publications of an individual doctor's medicare data set.

We have designed the data collection process to ensure that only alpha-numeric identifiers chosen by participating doctors and known only to them are used. These will be attached to error reports in the final files analyzed by the PIs. Therefore it will be possible for the researchers to conclude how many reports an individual doctor has contributed, but there will be no way of determining from where any report was submitted or linking a self-chosen PIN to a participant.

Data Security Measures

Privacy for participants will be ensured. The system has been designed to follow internationally recognized information security standards for highly sensitive information. In a system such as the one proposed there are three major risks to the security of participant data. The first is that the data may be intercepted while in transit between the GP and the system, the second is that there may be unauthorised access to the data stored on the system, and the third is that the anonymity of survey participants may be compromised. These concerns are addressed below.

The data interception risk is mitigated by employing industry standard encryption between the survey participant's computer and the system. The encryption is built into the operating system on all standard computers and does not require any configuration on the part of the user. The encryption will be enabled automatically when the participant begins completing a report.

The unauthorised access risk is mitigated by splitting the system into two parts - a webserver and a database server. The webserver is accessible from the internet and does not store any participant data. The database server is accessible only from the internal network of the web hosting company, and this is where the participant data is stored. Access to the database server will require a password. Both systems are protected by firewalls and both will be supplied with intrusion detection capabilities.

The compromise of anonymity risk is mitigated by identifying participants with an identification number of their own choosing. This number is known only to the participant. This method underwent successful trial in our pilot study. Thus the identity of participants is protected even in the highly unlikely event that the system security is compromised. Also, the web server logs will be purged on a periodic basis to prevent reconstruction of session information.

In addition to the techniques outlined above a service level agreement (SLA) will be entered into with the web hosting company. This SLA will enforce a required level of vigilance on the part of the web host company regarding the security of the system. This will ensure server patches are kept up to date, intrusion detection logs are checked, and physical security is maintained

At the conclusion of the study, the purging process by the Internet Service Provider will mean that the only copy of data will be held securely on CD Rom in the Department of General Practice, University of Sydney. The electronic collection of error reports is designed to maintain the confidentiality of participating doctors by the following procedures:

Data security

Information about your participation in this study that could identify you will be stored only on a paper list maintained in The Department of General Practice Sydney University. On completion of the study we will ask you whether you wish your contribution to this particular study to continue to be known. If you wish **not** to be known as a contributor to this study, we will expunge your name from the list of contributors. The computer program with which you record error data in your office overwrites error reports as you send them. Neither you nor anyone else will be able to access over-written files. Passwords and secure IDs will be used whenever anyone writes, reads, or analyzes error reports.

Encryption is achieved using proprietary technology with the encryption key held off-line.

New findings

When the data have been completed and analyzed, we will tell you about the new information we have regarding threats to patient safety in family practice. If we find any other similar information from other sources, we will also tell you about this.

Costs to you for participating

There are no costs to you for participating in the study. You will have to find a little extra time to submit the information on errors that may occur in your practice during the twelve month study period.

Payments to you for participating

You will be paid a total of \$200 + GST on completion of the study. This payment is based on a honesty system.

An application for RACGP Quality assurance audit points is pending.

Your rights as a participant in this study

Participation in this study is entirely voluntary. You have the right to cease contributing error data at any time. Leaving the study like this will not result in any penalty, loss of benefits, or your right to be involved in any other studies conducted by the Department of General Practice.

Problems and questions

If you have questions about the study, any problems, or think that something unusual or unexpected is happening, call Professor Michael Kidd or Dr. Meredith Makeham on (02) 9818 1400.

This study has been approved by the Human Research Ethics Committee of the University of Sydney. Any person with complaints or concerns about the conduct of a research study can contact the secretary of the Committee on, (02) 9351 4811

Withdrawal by investigator or sponsor

The investigators may stop the study or take you out of the study if you do not comply with the study plan. They may remove your reports from the study for various other administrative reasons. They can do this without your consent.

**Research Study: Investigating Threats to Australian
Patient safety in General Practice**

Participant's consent Form

I Dr. of

.....
have read and understood the information provided in this Consent Form and have discussed the study with

I have been made aware of the requirements of the study, including any known or expected inconvenience, or risk and their implications as far as they are currently known by the researchers.

I voluntarily agree to participate in this study.

I understand that I can withdraw at any time.

I also understand that the research study is strictly confidential.

I hereby agree to participate in this research study.

Participating Doctors signature

Date (written by doctor)

Doctors name (printed)

Witness's signature

Date (written by witness)

Witness's name (printed)

Signature of person taking consent

Date (written by person taking consent)

Name of person taking consent

A copy of this signed and dated form must be given to the participating Doctor.

This form must be retained in the Investigator file.

Appendix 3: Background questionnaire for GP participants

This appendix contains the background questionnaire that participating GPs completed prior to their commencement of the TAPS study. It was provided to them when they were first visited by a member of the study team and given the information and consent form. All participants completed and returned these details.

About You:

1. What is your age? ____
2. What is your sex? M F
3. For how many years have you worked as a GP (excluding training)? ____
4. In which RRMA group is your practice located? 1 2-3 4-7
5. What are your qualifications, including non-medical diplomas and degrees?

6. Did you study for your medical degree at an Australian University? Y N
7. Are you vocationally registered? Y N
If yes, do you hold an FRACGP? Y N
8. How many half days per week do you usually see patients? ____
9. In an average week, how many patients would you see in ½ a day of clinical work?

About Your Practice:

1. Is your practice accredited to qualify for PIP payments? Y N
2. Do you or any of the doctors in your practice teach medical students? Y N
3. Does your practice supervise GP Registrars? Y N
4. How many medical doctors see patients in your practice?

_____ _____
Number Number full time equivalent

5. How many other people (non-medical doctors) work in your practice?

_____ _____
Number Number full time equivalent

6. What are computers used for in your practice? (Choose all that apply).

- No computer in my practice
- accounting purposes generating lab or investigation requests or reports
- appointment schedules accessing journal articles
- keeping patient problem lists telemedicine consultations
- keeping patient medication lists electronic bulk-billing
- keeping all patient records e-mail
- generating prescriptions other (*please specify*) _____

Appendix 4: Taxonomy of patient safety events from Primary Care International Study of Medical Error (Makeham, Dovey et al. 2002)

This appendix contains the taxonomy of error that was published in the *Medical Journal of Australia* in 2002 resulting from the study entitled ‘The Primary Care International Study of Medical Error’ (PCISME). This pilot study taxonomy was the starting point from which the TAPS taxonomy was further developed.

Taxonomy of errors reported in general practice from PCISME (Makeham, Dovey et al. 2002)

1. Process Errors

1.1. Errors in Office Administration

- 1.1.1. Filing system errors
 - 1.1.2. Chart completeness errors
 - 1.1.3. Patient flow (through the health care system)
 - 1.1.4. Message handling errors
 - 1.1.5. Appointments errors
 - 1.1.6. Errors in maintenance of a safe physical environment
-

1.2. Investigation Errors

- 1.2.1. Laboratory errors
 - 1.2.2. Diagnostic imaging errors
 - 1.2.3. Errors in the processes of other investigations
-

1.3. Treatment Errors

- 1.3.1. Medication errors
 - 1.3.2. Errors in other treatments
-

1.4. Communication Errors

- 1.4.1. Errors in communication with patients
 - 1.4.2. Errors in communication with other health care providers (non-medical)
 - 1.4.3. Errors in communication with other doctors
 - 1.4.4. Errors in communication amongst the whole health care team
-

1.5. Payment Errors

- 1.5.1. Errors in processing insurance claims
 - 1.5.2. Errors in electronic payments
 - 1.5.3. Wrongly charged for care not received
-

1.6. Errors in Health Care Workforce Management

- 1.6.1. Absent staff not covered
 - 1.6.2. Dysfunctional referral procedures
 - 1.6.3. Errors in appointing after-hours workforce
-

2. Knowledge and Skills Errors

2.1. Errors in the Execution of a Clinical Task

- 2.1.1. Non-clinical staff made the wrong clinical decision
 - 2.1.2. Failed to follow standard practice
 - 2.1.3. Lacked needed experience or expertise in a clinical task
-

2.2. Errors in Diagnosis

- 2.2.1. Error in diagnosis by a nurse
 - 2.2.2. Delay in diagnosis
 - 2.2.3. Wrong or delayed diagnosis attributable to misinterpretation of investigations
 - 2.2.4. Wrong or delayed diagnosis attributable to misinterpretation of examination
 - 2.2.5. Wrong diagnosis by a pharmacist
 - 2.2.6. Wrong diagnosis by a hospital-based doctor
-

2.3. Wrong Treatment Decision with Right Diagnosis

- 2.3.1. Wrong treatment decision, influenced by patient preferences
- 2.3.2. Wrong treatment decision by doctor

Appendix 5: TAPS Report Description Summaries

Record Number	Report Time	Description
75	1/10/2003 1:21:49 PM	Topical steroid prescription item out of stock with pharmacy, GP not made aware resulting in patient having to return for different prescription
76	2/10/2003 12:43:03 PM	TEST REPORT - NO ERROR
77	3/10/2003 2:59:34 PM	TEST REPORT - NOT AN ERROR
78	3/10/2003 3:25:13 PM	Overuse of valium by reporting GP in management of status epilepticus in a NH patient, resulting in patient being considered overdosed with valium at a major hospital where he was referred by another doctor, and reporting GP under investigation by health department over the case
79	6/10/2003 9:50:23 AM	TEST REPORT - NO ERROR
80	6/10/2003 6:38:58 PM	TEST REPORT - NO ERROR
81	6/10/2003 10:36:29 PM	Delay in acting upon abnormal blood results resulting in possible delay in diagnosis of bowel cancer
82	6/10/2003 10:43:56 PM	Lipid lowering medication commenced at too high a dose and without warning patient of potential side effects or arranging review, resulting in patient suffering muscle aches and ceasing medication without consulting
83	7/10/2003 11:12:00 AM	Incorrect date given for ophthalmology out patient appointment by hospital
84	8/10/2003 7:13:06 AM	GP reports that Public Health failed to communicate an increased incidence of pertussis in area, and this contributed to a delayed diagnosis of pertussis in a child as GP's index of suspicion was not high for cases
85	8/10/2003 8:27:38 AM	GP misread a release of medical records request document in chart and thought patient was transferring to another GP when she was not
86	8/10/2003 1:56:45 PM	Locum prescribed medication for a patient without seeing her, in a case where her husband was seen with a likely STD, and did not want to tell
87	8/10/2003 3:15:37 PM	TEST REPORT - NO ERROR
88	9/10/2003 8:31:17 AM	Specialist reported result of VQ scan incorrectly, with misdiagnosis of pulmonary emboli, and patient took Warfarin and suffered side effects unnecessarily for 2 months
89	9/10/2003 4:08:01 PM	Recall systems failure resulting in missed taking a FBC to assess progress post treatment for Fe deficiency anaemia, and exacerbation of Angina
90	9/10/2003 6:20:44 PM	GP offended patient when advising she needed to lose weight
91	11/10/2003 12:18:40 PM	GP was administering pethidine regularly for recurrent migraine without authority for Drugs of Addiction
92	11/10/2003 12:27:26 PM	Recall system failure for prostate check-up, resulting in delayed

diagnosis of Ca prostate

93	12/10/2003 8:11:43 PM	Patient given incorrect medication during 9 day hospital admission of Provera instead of Hydrea (Rx of essential thrombocythemia), due to RMO misunderstanding GP phone advice on regular medications
94	13/10/2003 1:53:43 PM	GP incorrectly faxed confidential patient report to a wrong number, resulting in loss of patient trust and custom
95	16/10/2003 1:46:59 PM	Prescription error made using computer, forgot to state number of tablets to be given and computer failed to correct
96	16/10/2003 4:35:25 PM	Failed to secure needle to syringe which became detached during vaccine administration
97	17/10/2003 8:54:27 AM	Iatrogenic pneumothorax resulting from incorrect administration of pain relieving injection for fibromyalgia
98	20/10/2003 1:07:20 PM	TEST REPRT - NO ERROR
99	20/10/2003 1:45:34 PM	Near miss - GP was about to use a Hyfrecator to treat a skin lesion in a patient with a pacemaker
100	21/10/2003 1:20:00 PM	Poor discharge summary information to GP resulting in prolonged use of A drug which contributed to renal failure. Misdiagnosis of pneumonia. delayed diagnosis of metastatic malignancy involving lung and spine, primary unknown
101	22/10/2003 9:06:57 PM	Prescribed antimalarials to a patient on antiepileptic medn which could have resulted in serious interaction if patient had not gotten a second Opinion
102	23/10/2003 3:19:24 PM	Delay in obtaining important investigations due to lack of after-hours service in area
103	23/10/2003 5:41:40 PM	Used incorrect equipment when taking specimen for laboratory testing during minor surgery, resulting in accidental destruction of specimen
104	23/10/2003 8:28:59 PM	Mistake in noting past illness in medical records as Hep A instead of Hep B due to incorrect assumptions
105	28/10/2003 11:39:01 AM	Prescribed ear drops instead of eye drops accidentally
106	28/10/2003 11:44:20 AM	Incorrect management/treatment plan as a result of failing to review old records thoroughly during the consultation
107	29/10/2003 1:44:26 PM	Forgot to give patient prescription as planned during consultation
108	29/10/2003 11:14:05 PM	Failure to stabilise INR levels in warfarinised patient due to communication failures with poor patient understanding and medication changes by other doctors
109	30/10/2003 10:03:09 AM	Delayed diagnosis of subdural haematoma contributed to by local hospital staff resistant to investigation and treatment requests of GP
110	30/10/2003 10:25:59 AM	Pharmacist dispensed sandomigran instead of Visken accidentally
111	30/10/2003 3:23:52 PM	Patient referral to psychiatrist accidentally faxed to wrong number

112	31/10/2003 2:00:58 PM	Delayed diagnosis of severe bilateral bacterial pneumonia in NH patient, resulting in patient death
113	31/10/2003 2:37:00 PM	Omitted to follow up INR results/ failure to manage INR levels appropriately by GP in newly warfarinised patient, resulting in INR of 11
114	31/10/2003 6:36:19 PM	NOT AN ERROR - Oral contraceptive pill failure resulting in unwanted Pregnancy
115	1/11/2003 11:25:14 AM	Incorrect drug level range information given by hospital pathology department to GP for serum Lamictal, resulting in mistaken dosage adjustment of anti-epileptic medication
116	3/11/2003 2:30:47 PM	Hospital emergency resident incorrectly interpreted Xray and clinical signs in child with a fractured elbow, and discharged patient with a misdiagnosis of sprain
117	3/11/2003 4:38:04 PM	Forgot to put date on a previous entry in paper based medical records
118	5/11/2003 12:56:19 PM	Computer script printed with incorrect patient name due to wrong file being opened
119	5/11/2003 2:15:35 PM	NO ERROR REPORT
120	5/11/2003 6:02:09 PM	Incorrect patient details entered into computer records
121	6/11/2003 2:29:25 PM	Delay in receiving abnormal INR results from laboratory, who faxed to an unattended surgery on a Saturday afternoon
122	9/11/2003 4:02:13 PM	Incorrect dosage of blood pressure tablets accidentally prescribed using computer software
123	9/11/2003 5:20:27 PM	NO ERROR - TEST REPORT
124	10/11/2003 7:19:53 PM	Accidental incorrect dosage instructions on Actonel script resulting in patient taking a weekly medication daily, not corrected by computer prescribing package or pharmacist
125	11/11/2003 11:47:39 AM	Incorrect dosage information accidentally written on computer
126	11/11/2003 12:08:27 PM	TEST REPORT - FROM TAPS TEAM
127	11/11/2003 8:01:03 PM	TEST REPORT - not an error
128	13/11/2003 10:05:41 AM	Attributed abnormal MSU result to wrong patient with a similar name, treated wrong patient who was in a NH, plus had delay in treating original patient who had the abnormal result
129	13/11/2003 3:42:06 PM	Missed seeing a positive Chlamydia pathology result, treatment delayed
130	13/11/2003 6:21:40 PM	Delay in patient following through with referral for specialist consultation/ further investigations due to transportation difficulties and lack of bulk-
131	14/11/2003 10:18:50 AM	Hostel carer incorrectly administered medications to wrong patient

- 132 14/11/2003 5:18:53 PM Incorrect treatment for dislocated first MTP joint, initially failed to put into plaster as per standard practice, corrected next day
- 133 17/11/2003 11:35:13 AM Incorrectly spelled patient surname on PAP slide
- 134 17/11/2003 12:34:56 PM Delay in treatment of Fe deficiency anaemia possibly contributed to patient having a miscarriage of pregnancy
- 135 17/11/2003 1:01:30 PM Delay in assessing, diagnosing and treating patient with severe infective exacerbation of asthma due to GP time pressures resulting in poor triaging of seriously ill patient
- 136 17/11/2003 5:06:07 PM Failure to ensure patient with possible pneumothorax had had an urgent Xray, and then follow up urgent radiology over weekend
- 137 17/11/2003 9:02:56 PM Inadequate pain management of arterial ulcer, and failure to diagnose small vessel vasculitis by previous doctor
- 138 19/11/2003 9:19:44 PM Prescription for azithromycin written in previous patient's name using computer program
- 139 19/11/2003 9:31:42 PM Meningococcal C vaccine diluent given without active ingredient
- 140 19/11/2003 10:56:24 PM NO REPORT
- 141 20/11/2003 12:15:15 PM Poor technique in giving knee injection contributed to complication of Bursitis
- 142 20/11/2003 6:41:02 PM Meningococcal C vaccine diluent given without active ingredient
- 143 20/11/2003 6:55:54 PM Contraindicated medication prescribed to a patient on warfarin, causing INR to rise and serious abdominal bleed requiring hospitalisation, no computer warning because on home visit without access
- 144 24/11/2003 11:16:37 AM Failure to diagnose oesophageal foreign body causing chest pain, thought patient had oesophagitis in rushed consultation
- 145 24/11/2003 3:06:32 PM Radiology practice sent Xray report to wrong GP
- 146 25/11/2003 11:48:55 AM Delay in receiving pelvic ultrasound results when radiology practice forgot to send to requesting GP and had confusion over whether patient was to collect or they were to send films to practice
- 147 25/11/2003 1:59:15 PM Prescription written in wrong name from another patient's file with same surname using computer
- 148 25/11/2003 3:05:35 PM Incorrect medical management of menorrhagia
- 149 25/11/2003 3:14:10 PM Failed to recall patient with suspicious breast changes, lack of system at Practice
- 150 25/11/2003 3:22:48 PM GP did not remove panadeine forte from patient's regular medication list on computer when meant to cease it; GP's colleague didn't review previous notes in file and provided script for a ceased medn (panadeine forte) against regular doctor's orders

151	26/11/2003 10:45:55 AM	Wrong patient responded to call into consulting room; prescription issued in incorrect name
152	26/11/2003 10:55:45 AM	Wrong patient responded to call into consulting room; notes were entered into another patient's file
153	26/11/2003 6:11:48 PM	Delayed diagnosis of cardiomyopathy in complicated patient resulted in premature death
154	26/11/2003 6:26:55 PM	Faulty needle attachment to syringe caused failure of vaccination with vaccine spilling out; lack of attention to which vaccines are in which syringe with multiple immunisations, resulted in a vaccine having to be administered twice in the event of one of the syringes being spilt during Procedure
155	27/11/2003 9:49:22 AM	TEST REPORT - NO ERROR
156	27/11/2003 3:52:35 PM	TEST REPORT - NO ERROR
157	27/11/2003 8:55:39 PM	Failure of recall system for ECG result showing AF
158	27/11/2003 9:04:45 PM	Failed to communicate effectively to a patient that a cardiology referral for a second opinion was advisable, resulting in patient not arranging to See specialist despite letter being given
159	29/11/2003 7:12:28 PM	Prescription printed with incorrect patient name using computer when forgot to change file from previous consultation
160	30/11/2003 1:14:44 AM	Dropped and lost a used open vial when attempting to take to 'sharps' bin then stepped on it later
161	30/11/2003 1:29:35 AM	Forgot to attend NH patient for 2 days when called for urgent visit
162	30/11/2003 1:40:57 AM	Prescribed contraindicated drug against specialist advice because failed to review patient's notes thoroughly when reviewing another GP's patient
163	30/11/2003 4:14:29 PM	Prescribed a discontinued immunisation because was not informed it had been ceased
164	1/12/2003 7:12:16 AM	Needlestick injury to child during immunisation
165	1/12/2003 4:34:39 PM	Paper notes lost from patient file
166	1/12/2003 5:26:48 PM	Paper notes incorrectly ordered in file
167	3/12/2003 1:17:58 PM	Prescription given for an item no longer available on PBS
168	3/12/2003 1:23:17 PM	Inappropriate referral to a retired specialist
169	3/12/2003 4:38:12 PM	Radiologist missed possible Ca bowel on CT, picked up by reporting GP
170	7/12/2003 5:29:37 PM	Patient given antibiotic treatment incorrectly based on another persons path results misfiled in hospital notes
171	7/12/2003 5:44:16 PM	Prescription given for a discontinued antibiotic medication

172	9/12/2003 2:37:15 PM	Prolonged consultation because of incomplete records
173	11/12/2003 7:41:43 AM	Patient consultation delayed because GP unaware they were waiting
174	11/12/2003 4:26:16 PM	Patient records re: foot problem made in another patient's file with similar name, duplication of investigations needed at subsequent visit
175	15/12/2003 9:06:31 AM	NO ERROR - description of results processing computer vs paper
176	15/12/2003 9:30:24 AM	Incorrect DOB on computer file
177	15/12/2003 9:34:08 AM	Incorrect vaccination advice given
178	16/12/2003 11:06:05 AM	GP failed to process a Work Cover case, instead claiming a Medicare Consultation
179	16/12/2003 4:37:11 PM	Delayed diagnosis cardiac arrhythmia
180	18/12/2003 8:45:30 AM	Pathology results not matching patient name on practice computer file causing delay in care process
181	18/12/2003 1:41:22 PM	Incomplete details in patient's file meant no phone number to notify high INR result
182	18/12/2003 1:41:34 PM	Incorrect antibiotic medication dispensed by pharmacy resulted in tympanic membrane rupture
183	18/12/2003 1:46:31 PM	Contraindicated drug prescribed (allergy) in nursing home lacking computer warning system
184	19/12/2003 12:34:09 PM	Wrong DOB info in patient file transcribed to transfusion form
185	19/12/2003 1:56:50 PM	Incorrect medication charting in Nursing Home patient
186	23/12/2003 1:58:56 PM	Incorrect dose of warfarin prescribed
187	23/12/2003 7:10:52 PM	Lack of appropriate follow up of new ACE and new antipsychotic medications resulting in postural hypotension
188	23/12/2003 7:23:31 PM	Failed to follow up newly commenced warfarin after dc from hospital, resulted in nose bleed
189	23/12/2003 11:18:04 PM	Failure of medical colleague to provide appropriate hospital care post Trauma
190	23/12/2003 11:27:15 PM	Failed to appropriately apply pressure post venesection resulting in minor post procedure bleed for patient
191	24/12/2003 12:27:21 PM	Delay in diagnosis of Ca Breast and incorrect interpretation of Mammogram by radiologist
192	24/12/2003 12:47:45 PM	Hip fracture hours after inappropriate discharge of elderly frail patient having falls from overcrowded ED
193	27/12/2003 10:42:03 AM	Prescription error incorrect steroid dose for asthma treatment

194	29/12/2003 10:25:18 PM	Wrong BP medication dosage dispensed
195	30/12/2003 9:35:31 AM	Inadequate info on hospital discharge to provide appropriate care to post partum bleed
196	30/12/2003 3:37:25 PM	Incorrect patient info on path referral form
197	30/12/2003 5:26:42 PM	Incorrect date on sick leave certificate
198	1/01/2004 11:37:11 AM	Pathology lab made incorrect reading of BHCG results and nearly caused a misdiagnosis of death in utero with D&C
199	1/01/2004 11:50:51 AM	Pharmacy dispensing error of wrong dose BP medn
200	1/01/2004 12:11:44 PM	Delay in hospital admission for serious illness of gangrene of foot due to bed pressures in system and eventual ED referral
201	3/01/2004 3:08:32 PM	Consultation carried out with incorrect patient file and name due to patient responding to another's name in waiting room and during consultation; scripts written with incorrect name; scripts dispensed with correct name, but pharmacist failed to inform GP that written in another name
202	5/01/2004 5:54:02 PM	INR problem due to commencement of frusemide and failure to adequately monitor
203	6/01/2004 6:00:52 PM	Hospital cancelled patient waiting for colonoscopy due to communication problem when patient meant to delay procedure due to intercurrent illness
204	6/01/2004 6:10:43 PM	Physician prescribed incorrect treatment for hypertension in pregnant
205	8/01/2004 8:49:00 AM	GP failed to pick up high risk labour due to failing to check CTG
206	8/01/2004 5:27:58 PM	Pharmacist failed to dispense prescribed medication for new diabetic requested by patient, didn't inform GP
207	9/01/2004 8:25:51 AM	Pharmacist illegally supplying a benzodiazepine without prescription for many years, and patient suffered withdrawal when ceased using it
208	9/01/2004 1:06:47 PM	BP medn orders from physician not followed accurately by patient
209	9/01/2004 2:03:40 PM	Radiology failed to deliver results of abdominal US screening for Ca ovary (electronically)
210	12/01/2004 5:15:37 PM	Incorrect medication dispensed by pharmacist
211	13/01/2004 6:39:38 PM	Pharmacist failed to dispense prescribed medication for new diabetic requested by patient, and didn't inform GP
212	13/01/2004 10:48:14 PM	Hospital nursing staff incorrectly administered antibiotic treatment order for cellulitis of leg
213	14/01/2004 3:08:08 PM	Delayed implementation of anticoagulation/INR management in post op DVT; reception staff incorrect admin procedures with booking path results
214	14/01/2004 6:36:51 PM	Pathology lab failed to carry out Rh antibody screen as ordered

215	15/01/2004 11:11:45 AM	(Two separate patients) failed to adequately investigate irregular pulses due to time pressures resulting in 1. severe SOB and 2. CCF and admission to hospital
216	15/01/2004 11:35:40 AM	Delay in provision of PAP smear possibly due to male GP and patient Discomfort
217	17/01/2004 5:29:38 PM	Delay in specialist communicating abnormal results after endoscopy caused treatment delay
218	20/01/2004 11:12:22 AM	Wrong type of Insulin medication prescribed at patient request, with GP failing to consider the medication was inappropriate
219	20/01/2004 12:59:32 PM	TEST REPORT – NO ERROR
220	20/01/2004 5:37:29 PM	Delayed diagnosis of cellulitis of foot due to inadequate examination
221	21/01/2004 7:04:27 PM	Delayed reporting of abnormal sinus CT showing possible tumour
222	21/01/2004 7:09:45 PM	Failure to diagnose SAH resulted in death of patient
223	22/01/2004 11:18:09 AM	Ruptured tympanic membrane as a result of ear syringing
224	28/01/2004 10:24:31 AM	Patient left without being seen after MVA due to payment issue
225	28/01/2004 9:06:42 PM	Incorrect patient file used for consultation requesting IVF referral
226	29/01/2004 8:52:47 AM	Consultation notes made in another patients file with similar name; script written with incorrect name
227	29/01/2004 11:26:11 AM	Mistakenly applied fluorescein to contact lens in examination
228	31/01/2004 5:15:59 PM	Nursing home staff failed to follow antibiotic medn order correctly
229	31/01/2004 5:36:30 PM	Nursing home staff failed to follow Celebrex medn order correctly
230	31/01/2004 5:50:17 PM	Prescribed antibiotic ear drops instead of eye drops
231	31/01/2004 6:48:06 PM	Prescribed antibiotic ear drops instead of eye drops
232	2/02/2004 3:24:21 PM	Incorrect antibiotic dose prescribed for infant with tonsillitis
233	3/02/2004 2:38:49 PM	Patient given contraindicated antibiotic - allergic
234	3/02/2004 3:38:16 PM	Mismanagement of Warfarin resulting in elevated INR and bruising
235	9/02/2004 5:12:53 PM	Practice buildings disrepair caused patient accident
236	11/02/2004 12:18:50 PM	Wrong patient details on path referral
237	11/02/2004 1:32:14 PM	Patient presents late for contraceptive injection
238	11/02/2004 4:49:44 PM	Recall system failure results in late treatment of significant condition
239	12/02/2004 8:27:27 AM	Incorrect patient name details on computer records

240	12/02/2004 8:29:54 AM	Incorrect patient address details on computer records
241	12/02/2004 8:31:58 AM	Incorrect patient Medicare/insurance details on computer records
242	14/02/2004 10:43:46 AM	Abnormal pathology result not reported to patient, abnormal pathology result not followed up by GP appropriately
243	16/02/2004 8:59:14 AM	Interaction between antibiotic for cellulitis and warfarin, and failure to appropriately monitor INR over weekend resulting in hospital admission
244	17/02/2004 8:27:35 AM	Extra vaccination injection accidentally given
245	17/02/2004 2:22:16 PM	Incorrect INR result given to patient, patient result incorrectly filed in another patient's chart
246	18/02/2004 11:36:37 AM	Incorrect medication prescribed, quinidine instead of quinine, computer script writing mistake
247	18/02/2004 1:40:50 PM	Gave a clozaril prescription without FBC results available
248	23/02/2004 12:11:13 PM	Incorrect date on 'forms'
249	24/02/2004 5:57:26 PM	Dizzy patient incorrectly diagnosed as depression rather than arrhythmia, patient incorrectly advised to cease cardiac medications causing hypertension and exacerbation of arrhythmia, adverse effects of antidepressant medication
250	25/02/2004 3:51:34 PM	No records available whilst seeing patient, due to practice moving locations and sharing files with an associate
251	26/02/2004 4:48:37 PM	Patient reported abnormal pathology results ordered by another GP as being normal, abnormal results could not be given to patient due to lack of contact details
252	29/02/2004 10:50:31 PM	Failed to communicate dose change of warfarin to patient
253	1/03/2004 10:32:10 PM	Failure by hospital Dr to correctly investigate, diagnose and treat referred gastroenteritis case from GP
254	1/03/2004 10:43:42 PM	Respiratory arrest and ongoing PTSD due to morphine overdose on malfunctioning PCA machine
255	2/03/2004 10:39:00 PM	Misdiagnosis of SCC on thumb
256	4/03/2004 8:53:56 AM	Pathology results misfiled in computer system, patient didn't receive them
257	4/03/2004 12:21:20 PM	NO ERROR - STORY ABOUT VACCINES
258	4/03/2004 12:26:16 PM	Warfarin mismanagement resulted in haemoptysis
259	4/03/2004 12:58:47 PM	Warfarin mismanagement resulting in low INR
260	6/03/2004 12:41:21 PM	GP failed to give abnormal path results to patient who was told there were normal, leading to delayed diagnosis and treatment of endocrine disorder
261	6/03/2004 5:54:24 PM	Path request printed with incorrect patient details

262	8/03/2004 4:24:06 PM	Prescribed a medn for a patient that had been discontinued by specialist, picked up by pharmacist
263	8/03/2004 5:57:08 PM	Pharmacist failed to dispense metformin script
264	8/03/2004 6:13:34 PM	Incorrectly charted medication in hospital
265	8/03/2004 6:14:57 PM	NOT AN ERROR
266	8/03/2004 6:59:05 PM	Warfarin mismanagement INR too high, then excision of skin lesion without checking INR resulted in oozing and hosp admission
267	8/03/2004 7:09:52 PM	GP posted another patients report by physician and had no info when seeing his/her patient
268	8/03/2004 7:24:59 PM	Enema given to severely neutropaenic patient, contraindicated practice
269	8/03/2004 7:42:09 PM	Long delayed treatment of gastritis due to failure of specialist to communicate gastroscopy results with GP
270	9/03/2004 5:18:31 PM	Delayed diagnosis/treatment of skin lesion requiring excision
271	9/03/2004 6:46:29 PM	Incorrect dose of antihypertensive medn dispensed at pharmacy
272	10/03/2004 9:09:23 AM	Prescribed a contraindicated medn (Tramal) to patient on an SSRI causing serotonergic syndrome despite MD
273	10/03/2004 12:08:45 PM	Warfarin mismanagement; gave Daktarin oral gel to patient on warfarin, on home visit without computer to missed interaction, high INR and hospital admission required
274	10/03/2004 9:16:47 PM	Misdiagnosis of atopic eczema resulting in patient experiencing adverse effects of unnecessary antibiotic medn
275	10/03/2004 9:26:58 PM	NOT AN ERROR - adverse effect of morphine appropriately prescribed
276	15/03/2004 6:28:15 PM	Patient discharged from hospital with no follow up arrangements and staples still in wound post-op
277	16/03/2004 10:47:47 PM	Patient given 60mg of Morphine rather than 20mg by mistake intra-Operatively during emergency LSCS
278	18/03/2004 12:22:55 PM	GP missed a report of an abnormal nuchal fold result, patient didn't find out until 16 weeks of any problem
279	19/03/2004 1:12:06 PM	Computer prescription written with incorrect patient name
280	19/03/2004 1:19:14 PM	Missed reading MSU results and UTI worsened in NH patient
281	25/03/2004 1:35:07 PM	GP unable to admit psychiatric patient requiring admission due to lack of mental health beds
282	26/03/2004 2:52:57 PM	Warfarin mismanagement; hospital discharged patient commenced on warfarin post MV replacement with no safe follow up plan in place
283	26/03/2004 4:21:01 PM	Delayed diagnosis of glioblastoma with normal CT brain due to MRI not

		being performed earlier
284	29/03/2004 9:55:28 AM	Computer technical problems resulted in loss of online Australian Medicines Handbook for several months
285	29/03/2004 12:12:59 PM	Perforated colon, peritonitis, ileostomy and protracted admission as result of endoscopy
286	30/03/2004 12:34:24 PM	Missed giving HIB vac to 4 mo old due to confusion resulting from new computer template on MD software
287	30/03/2004 12:40:04 PM	Consultation report from a/hours locum reported giving pethidine to child with throat infection when child had not been given any
288	31/03/2004 2:29:57 PM	Patient ceased progesterone HRT component and had PV bleeding due to misunderstanding GP instruction
289	31/03/2004 2:39:20 PM	Incorrect advice given to patient by GP regarding prognosis of complex health problem, AS and Ca lung resulting in failure to treat Ca optimally
290	7/04/2004 3:48:55 PM	Patient injured by surgery furniture (cut leg on exam. couch)
291	11/04/2004 11:48:11 AM	Practice nurse overloaded with verbal instructions from GPs and nearly gave incorrect injection, changed to written
292	11/04/2004 11:56:28 AM	Warfarin management problem and INR elevated, multiple docs involved contributing to problem
293	11/04/2004 12:03:20 PM	Contraindicated medication prescribed (penicillin in allergic patient, hand written notes being used)
294	11/04/2004 12:13:43 PM	Delayed treatment of child with potential testicular torsion due to message handling problems
295	14/04/2004 4:22:15 PM	Incorrect repeat prescription given, communication problem
296	14/04/2004 10:42:29 PM	Patient given injection for muscle spasm into wrong leg
297	20/04/2004 1:41:34 PM	Patient had inadequate discharge planning, resulting in refracture of hip after THR on day 2 post d/c
298	20/04/2004 2:03:18 PM	Patient suffered vasovagal after lignocaine injection for minor procedure
299	20/04/2004 6:12:19 PM	Dementia patient from UK inappropriately placed in hostel by family due to cost of nursing home, fractured hip when fell from bed due to level of
300	21/04/2004 4:34:09 PM	Anxiety symptoms of patient worsened after switching from Cipramil to Lexapro
301	22/04/2004 10:14:08 AM	Mistaking identity of patient, GP made inappropriate comment about relationship problems with husband
302	22/04/2004 9:48:25 PM	Wrong patient given antibiotics, correct patient had delay in treatment, due to misfiling of MSU report
303	26/04/2004 11:48:34 AM	Patient prescribed out of stock item

- 304 27/04/2004 11:47:41 AM Misdiagnosis of GORD, delayed diagnosis of cholecystitis/cholelithiasis by hospital ED over 18 months
- 305 1/05/2004 9:07:22 PM Failure of follow-up high blood glucose/ pathology result, patient presented to ED with hyperglycaemia
- 306 1/05/2004 9:24:20 PM Pharmacist dispensed incorrect dose Epilim
- 307 6/05/2004 7:18:07 AM Pharmacist incorrectly dispensed Mogadon instead of Maxalon, patient Sedated
- 308 6/05/2004 7:41:40 AM Misdiagnosis of hypothyroidism by another GP, delayed diagnosis of
- 309 6/05/2004 7:54:09 AM Delayed diagnosis of Mycoplasma pneumonia in child
- 310 8/05/2004 2:22:43 PM Perforated tympanic membrane as a result of ear syringing
- 311 8/05/2004 2:41:28 PM General thoughts on ethics of investing in companies that return profits influencing choices of patient care
- 312 11/05/2004 11:04:08 AM Pathology reports that skin ca excisions narrow or incomplete, but on re-excision no residual disease found and patient therefore underwent unnecessary minor surgery
- 313 11/05/2004 1:29:29 PM Incorrect dose of morphine given in nursing home
- 314 11/05/2004 1:49:48 PM Lab phoned INR to practice; message taking problem at reception resulted in incorrect dose adjustment of warfarin
- 315 11/05/2004 2:59:55 PM Patient complaint "GP trawling for business" because GP sent recall letter for BP check, when check was not done at visit in previous week about unrelated matter. GP felt his/her computer recall system being used more effectively could have prevented.
- 316 11/05/2004 3:09:21 PM Patient inappropriately treated with antipsychotic medn when actually had depression with no psychotic features
- 317 11/05/2004 4:32:27 PM Rabies vaccine recall by company and patients required to have further 2 injections due to live virus found in related batch
- 318 11/05/2004 6:58:25 PM Patient discharged from hospital inappropriately post-operatively, possibly after a fall and CVA within 24 hrs post -op at the hospital; cancellation of surgery caused extended period off aspirin possibly contributing to a CVA
- 319 11/05/2004 7:02:34 PM prescription error on computer, failed to provide adequate quantity of medn, lack of checking printed material
- 320 11/05/2004 11:40:02 PM Failure to appropriately examine patient with chest pain in psychiatric hospital caused delay in diagnosis of shingles and inadequate treatment
- 321 11/05/2004 11:45:18 PM Pharmacist dispensed incorrect dose of Prothiaden, patient experienced severe side effects of increased medn
- 322 12/05/2004 4:27:49 PM GP has inadequate follow-up systems to ensure requested investigations are done and patients appropriately followed up. GP gave example of patient who had not had lipids and resting ECG ordered as screen, and

then during chest pain presented for requested ECG

- 323 13/05/2004 1:19:03 PM Failed to contact patient and arrange further care following an abnormal mammogram, delay of 1 month until patient contacted GP for result
- 324 14/05/2004 1:04:41 PM Incorrect Xray films given to patient and incorrect referral written based on these, same surname different first names
- 325 18/05/2004 8:59:59 AM Prescription written on computer with previous patients name
- 326 18/05/2004 11:38:44 PM Local hospital nursing administration refused to accept transfer due to cost of extra nursing staff to open a bed resulting in distress, cost and inconvenience for family
- 327 18/05/2004 11:46:29 PM Pharmacist told patient that no medn scripts left, when authority repeats had been provided by GP
- 328 18/05/2004 11:56:44 PM Patient failed to attend urologist after referred for a raised PSA, and no recall in place to check that significant pathology (PSA) was followed up
- 329 19/05/2004 10:29:42 AM Delay in examination and treatment of skin cancer in nursing home patient due to hospital specialist who was on leave being sent request from nursing staff to see lesion rather than GP, and no communication to GP from NH or hospital
- 330 19/05/2004 3:06:52 PM Poor recall system and patient education resulted in 5 year F/U post Ca gall bladder CT scan not being organised, and subsequent Ca of pancreas developed which may have been found at an earlier stage if this scan was routinely performed.
- 331 19/05/2004 6:47:16 PM Recurrent problem of choosing wrong dosage of medication from computer drop down list, usually picked up by pharmacist
- 332 20/05/2004 12:39:24 PM SAH and parietal skull fracture post trauma missed by both ED on day of injury and another GP 2 days later, patient seen by reporting GP day 3 who investigated and diagnosed correctly
- 333 21/05/2004 1:25:53 PM Pharmacist dispensed incorrect medication - Lasix instead of Lipex
- 334 21/05/2004 1:31:53 PM Patient given incorrect medication in hostel webster pack for 2 days after staff and pharmacist failed to make adjustments after GP changed
- 335 21/05/2004 5:57:38 PM Patient sent for unnecessary lumbar spine Xray one month after already had this test, due to GP incorrectly completing request form when had meant to request lumbar CT
- 336 21/05/2004 11:55:44 PM Young woman with severe pneumonia inappropriately managed (wrong medication regime) by hospital VMO when initially referred to district
- 337 22/05/2004 10:07:11 AM Incorrect patient computer file opened and used during consultation due to similar names
- 338 23/05/2004 10:13:24 PM Incorrect dose of prednisone dispensed by pharmacist resulting in 6 week delay in symptom control of rheumatoid arthritis
- 339 24/05/2004 11:36:00 AM Incorrect management of Ca breast with lumpectomy initially undertaken rather than mastectomy, due to incorrect interpretation of initial investigations, patient requires more surgery

- 340 24/05/2004 2:16:45 PM GP on call was not able to be contacted overnight resulting in delay for patient needing medical attention, inconvenience for ambulance, hospital nursing staff and second doctor
- 341 24/05/2004 6:21:05 PM Pharmacist dispensed out of date typhoid vaccines to two patients
- 342 24/05/2004 7:09:33 PM Patient had elective surgery TURP cancelled unnecessarily when hilar lymphadenopathy was seen on CXR, then sent for a CT, however due to lack of old written records not being readily visible on computer record system in practice, it was missed that this was known about and investigated nearly 10 years previously and there was no change from the previous investigations
- 343 24/05/2004 7:16:34 PM Incorrect dosage of medication selected from computer drop down list in prescribing software for antimalarial treatment
- 344 24/05/2004 10:09:47 PM Fatal haemorrhage in patient with terminal disease due partly to warfarin mismanagement and over-anticoagulation, INR not checked when medn Changed
- 345 25/05/2004 11:44:54 AM Same childhood immunisation given twice by mistake
- 346 26/05/2004 5:35:07 PM Patient sat in blood contamination on patient chair in doctor's office after venipuncture of previous patient. The patient failed to hear GP say not to sit down when GP noticed the blood and left the room to attend first patient and get cleaning organised.
- 347 27/05/2004 1:11:25 PM GP missed reading complete pathology report with a positive syphilis serology, delay of 2 weeks in informing patient
- 348 27/05/2004 3:43:32 PM Patient on warfarin requiring home collection for INR delayed for 4 days and was under-anticoagulated during this wait, due to reception/pathology miscommunication and a second patient of NESB (not on warfarin) being visited by mistake and having INR taken
- 349 29/05/2004 11:54:36 AM Pharmacist dispensed incorrect dose medn resulting in double amount prescribed being taken by patient
- 350 29/05/2004 12:11:19 PM Delayed diagnosis of urinary retention with overflow, misdiagnosed and managed as recurrent UTI due to inadequate examination
- 351 30/05/2004 4:07:06 PM Difficult to get timely specialist appointments in this region for neurology, ENT, paediatrics and obstetrics
- 352 30/05/2004 4:15:40 PM Delay in management of torticollis in neonate due to local hospital appointment records poorly kept and patient turned away by reception
- 353 30/05/2004 4:25:07 PM Unable to obtain angiograms for high risk cardiac patients in a timely manner in this region, waiting 6 weeks privately and 2 months publicly
- 354 30/05/2004 4:29:24 PM Local hospital staff refused to give information about patient's progress to the patient's GP, citing "privacy act" as reason
- 355 30/05/2004 4:34:44 PM Poor follow-up arrangements for patient with Ca kidney post hospital discharge after nephrectomy, with no information on histopathology being sent to GP, and surgeon going on leave

- 356 30/05/2004 6:20:31 PM Pharmacist dispensed Lanoxin 250 mcg instead of 62.5 mcg; error picked up by patient's wife prior to medn being taken
- 357 31/05/2004 12:16:32 PM Problem with downloading Xray results to patient record electronically, and potential for delay in appropriate management with serious consequences had the patient not re-presented with hard copy
- 358 31/05/2004 12:45:55 PM Hospital resident in ED missed Colles fracture of forearm on Xray, and failed to check formal report from radiologist, resulting in delay in
- 359 31/05/2004 1:21:07 PM Pharmacist incorrectly dispensed Zantac syrup to child instead of Ventolin syrup. Patient had been administered medn by mother before picked up by pharmacist and rectified
- 360 31/05/2004 1:35:59 PM Sudden death of patient for unknown reason; in previous 24 hours had INR reading of 6.8 and refused to attend hospital when contacted that evening by reporting GP, morning of death was given a subcut Vit K injection by usual LMO when continued to refuse to attend hospital. Reporting GP speculates that possible self harm and missed diagnosis of depression could be cause of death.
- 361 31/05/2004 1:46:50 PM Warfarin mismanaged by patient (?and another GP), resulting in INR of 5.8 untreated for 2 weeks. GP comments "warfarin therapy is a nightmare!"
- 362 31/05/2004 10:24:30 PM GP failed to diagnose extensive DVT for 4 days, picked up by colleague
- 363 31/05/2004 10:38:44 PM GP left a/hours message to contact him/her via local hospital; Poor Communication between GP on call and hospital staff answering phone after hours in ED; GP unable to be contacted because hospital staff didn't know his or her whereabouts or contact details.
- 364 31/05/2004 10:52:32 PM Delayed diagnosis of lung cancer with chest wall pain mimicking Radiculopathy
- 365 3/06/2004 2:19:28 PM Prescription printed with incorrect name using computer, forgot to change patient file, family member with same surname being seen at same time
- 366 3/06/2004 2:25:51 PM Was using incorrect patient computer file of patient with same name for some of consultation; new software doesn't display address
- 367 3/06/2004 10:25:05 PM GP forgot to do a home visit due to staff forgetting to put out patient file, no standard booking system in place; visit delayed for a day
- 368 6/06/2004 3:58:01 PM Patient had prolonged period of NBM and an unnecessary cannula left in wrist for 24 hours due to communication failure between radiologist and nursing staff after a CT at base hospital
- 369 6/06/2004 4:17:27 PM Misdiagnosis of fractured NOF by orthopaedic surgeon based on misinterpretation of CT resulted in pain for patient, incorrect management, weight bearing and eventual disintegration of fracture 5 days later requiring more complex surgery and possibly poorer outcomes
- 370 6/06/2004 6:04:44 PM GP prescribed a medication that was out of stock at pharmacy, substitution provided by pharmacist (Donnatabs instead of Donnalix), but GP feels no system in place for letting them know about out of stock

- 371 7/06/2004 11:11:31 AM Incorrect management of head injury with LOC by ED at major teaching hospital; failed to do neuro obs, clean wound properly, provide antibiotic cover or give instructions re what to consider post trauma or to do if headaches/ symptoms persist
- 372 7/06/2004 12:19:26 PM Incorrect patient details written on file resulted in misinformation to pharmacy and pathology
- 373 7/06/2004 12:37:01 PM Incorrect management of chest pain by GP on home visit; no ECG, left at home in pain, no follow-up, on BG of SVT and CCF, possible further AMI and cardiac deterioration
- 374 7/06/2004 3:17:47 PM Patient prescription printed with incorrect name from previous patient's computer file
- 375 9/06/2004 1:34:05 PM Radiologists providing conflicting reports on CT scan findings
- 376 10/06/2004 2:58:19 PM Recall system failed in that GP called same patient back twice by mistake to discuss results (CIN3 on Pap)
- 377 10/06/2004 3:03:58 PM Pathology Lab performed incorrect test on specimen sent (MCS instead of drug screen on urine sample)
- 378 10/06/2004 11:39:31 PM NO ERROR - lost info, TAPS website related
- 379 11/06/2004 9:49:53 AM Reception staff incorrectly gave out confidential medical information by
- 380 11/06/2004 10:03:22 AM Patient took double doses of medication after hospital discharge due to poor education from hospital staff and generic medication brands supplied duplicating meds at home
- 381 11/06/2004 10:20:49 AM Incorrect pathology request form provided with PAP slide due to printing request from previous patient's computer file
- 382 11/06/2004 11:24:03 AM Child fell off examination couch with GP present writing notes when mother left room to attend another child; no injury
- 383 11/06/2004 5:58:07 PM Patient had serious injury to leg/ deep laceration requiring hospitalisation when getting down from GP examination couch
- 384 13/06/2004 8:53:58 AM Patient prescribed a contraindicated medication; GP noted allergy but forgot about it later on during consult when writing script; pharmacy
- 385 13/06/2004 7:49:44 PM GP felt he/she had placed too much pressure on practice staff to complete 'tasks' (?administrative) and not seen to patient's medical outcomes with delay in instituting management
- 386 13/06/2004 8:00:16 PM GP feels guidelines around abnormal PSA and LFTs are not clear enough and causing management dilemmas
- 387 15/06/2004 12:36:33 PM Patient given another person's lab results and incorrect advice
- 388 15/06/2004 3:48:18 PM Hospital missed diagnosis of pneumonia in patient assessed in ED; hospital failed to follow up CXR results on test they ordered; hospital failed to forward test results to GP; patient's treatment of pneumonia was delayed by 2 weeks

- 389 16/06/2004 10:33:00 AM ED Dr failed to order CXR in patient with SOB and multiple probs; Incorrect diagnosis of LVF made by ED Dr in patient with small cell carcinoma; inadequate discharge communication with GP and no follow up arrangements made by ED; CXR ordered by GP after representation with stridor and SOB was incorrectly reported by Radiologist missing mediastinal mass nodes
- 390 17/06/2004 6:58:40 PM Incorrect lab result reported on methadone urine screen
- 391 19/06/2004 8:59:44 PM Abnormal pathology result (TSH) missed by GP; practice staff told patient abnormal result without GPs knowledge even though hadn't been signed off by GP; delay in treatment of hypothyroidism
- 392 19/06/2004 9:06:13 PM Patient in Nursing home on two similar medications (omeprazole and ranitidine) by mistake, GP didn't check medn carefully when recharting
- 393 20/06/2004 12:24:16 PM Issued prescription in incorrect patient name
- 394 20/06/2004 4:42:24 PM Lack of advice given to patient regarding managing potential side effects of new antidepressant medication
- 395 22/06/2004 12:26:50 AM Patient consultation recorded in another patient's computer file with same name; prescription issued for patient with wrong address details; two patient's with same names issued scripts from same computer file, both left scripts at same pharmacy at same time, and all medication collected by the patient with correct address details (problem picked up by pharmacist when second patient returned for medication that had been collected by someone else)
- 396 22/06/2004 12:42:17 AM unsterilised equipment used in ear syringing resulting in patient contracting otitis externa
- 397 24/06/2004 11:51:04 AM Patient details incorrectly entered into computer resulting in test results not downloading correctly to patient file
- 398 24/06/2004 4:11:00 PM Problems with implementing new computer business management programme, lack of support, staff and patients irate and waiting
- 399 29/06/2004 9:21:19 AM Incorrect treatment decision for cellulitis by hospital Dr; incorrect investigations for cellulitis taken by hospital doctor; incorrect information on hospital discharge summary
- 400 30/06/2004 11:38:47 PM GP missed reading FBC results in patient requiring transfusion, treatment delayed by 3 weeks, receptionist filed result without Dr initials
- 401 5/07/2004 1:24:09 PM GP failed to check UECs after starting ACE and CRF worsened
- 402 5/07/2004 10:29:25 PM Patient died of renal failure as complication of COX2 for pain management on background of complex medical problems. GP felt may be error in whether patient understood risks associated with the drug, also error in not involving specialists earlier for management advice
- 403 5/07/2004 10:37:11 PM Hospital discharged patient with inadequate supply of medication; hospital failed to educate patient about new medication regime, thus inadequate treatment until GP attended 2 days post discharge
- 404 6/07/2004 8:46:20 PM Receptionist issued incorrect receipt and patient was unable to claim

		correct Medicare rebate
405	7/07/2004 9:48:32 AM	Patient self-medicated with wife's antibiotics resulting in allergic reaction itch and angioedema, cross reaction with Ceclor/penicillin
406	7/07/2004 3:34:55 PM	GP collected blood test for PTH in wrong tube
407	8/07/2004 1:18:12 PM	Failure to follow up abnormal MSU in pregnant patient. Failure to treat UTI in pregnant patient, resulting in pyelonephritis
408	8/07/2004 1:23:42 PM	Incorrect management of abnormal screening GTT in pregnancy, patient did not have formal follow-up investigation or diabetic education, and was hyperglycaemic in late pregnancy
409	8/07/2004 5:20:44 PM	Incorrect lab result reported leading to patient believing non-viable
410	11/07/2004 4:41:20 PM	MSU failure to follow up abnormal result and child with abdo pain not treated - sent result to wrong specialist and didn't follow up with patient
411	11/07/2004 4:59:14 PM	Private hospital ED physician inappropriately discharged a seriously ill head injured patient who presented there. ED told GP who called to complain (when family later informed him/her of situation) that it was due to no beds, and patient went home bleeding and drowsy with a subdural
412	13/07/2004 6:10:38 PM	Communication failure with NESB patient, resulted in failure to comply with medn dosage instructions in cardiac failure treatment and serious cardiac event
413	13/07/2004 6:17:51 PM	Incorrect drug prescribed due to wrong choice from computer drop down list; incorrect number of repeats issued due to default setting on computer program
414	14/07/2004 2:22:44 PM	Insufficient follow up procedures in place and pathology result of anaemia not appropriately followed, related to poor understanding of computer program
415	14/07/2004 2:35:26 PM	Inadequate investigation, diagnosis and treatment in ED for Hydronephrosis and ureteric obstruction, in presence of newly diagnosed uterine cancer which was the underlying problem - GP had made diagnosis but presumes hospital Dr didn't read referral letter and failed to treat threatened kidney appropriately
416	15/07/2004 10:05:51 AM	child given 4yo immunisations twice by mistake, absence of 'blue book'
417	16/07/2004 12:35:12 PM	NO ERROR REORTED
418	18/07/2004 8:40:54 PM	Failure of medical services to be culturally accessible or acceptable to aboriginal patient - resulting in development of likely metastatic bowel cancer over three years. Original error was failure of patient to follow up on abdo mass with surgical referral, then 3 years later a failure for patient to accept investigation and treatment recommendations when presented to hospital with likely metastatic Bowel Ca
419	19/07/2004 2:42:20 PM	Delayed diagnosis of abdominal hernia in pregnant patient perhaps due to insufficient care with examination
420	19/07/2004 10:48:14 PM	Patient discharged from hospital with no medn and no understanding of new medn regime, with some medns missed by patient until GP visit day

- 421 19/07/2004 10:56:34 PM Inadequate information in hospital discharge summary - failed to inform of a blood transfusion post-operatively
- 422 19/07/2004 11:11:47 PM Patient given a referral to specialist in mother's name, had to be rewritten and faxed over
- 423 21/07/2004 2:47:23 PM NH staff gave a medication which had not been ordered
- 424 21/07/2004 2:50:27 PM Medication ceased by GP, but continued to be given by NH staff
- 425 21/07/2004 6:15:46 PM Government agency requesting confidential patient information without patient's consent
- 426 23/07/2004 2:15:00 PM Consultation notes entered into another patient's file with same name, but as new patient, no contact details known
- 427 28/07/2004 2:18:10 PM Pharmacy dispensed medication for a patient in her husband's name, who could have inadvertently taken it with his multiple other meds
- 428 28/07/2004 7:07:40 PM Patient suffered BP medn side effect (bradycardia) from interaction contributed to by GP failure to adjust other medn
- 429 28/07/2004 7:10:48 PM Patient was assessed by ED although had contacted GP office first and should have been advised to come there for assessment, due to poor phone triage procedures at practice
- 430 29/07/2004 4:10:10 PM NH home patient in abdominal pain left unattended by staff overnight
- 431 29/07/2004 4:20:33 PM GP had to return to NH as had charted meds incompletely
- 432 29/07/2004 9:16:57 PM prolonged wait for angiogram in uninsured patient, fault with cardiologist's booking procedures with this patient group
- 433 1/08/2004 7:25:59 PM GP generated computer script with incorrect dose of antihypertensive medication by pulling up an old one and changing date rather than generating new one; patient noticed mistake due to weaker strength tablet being different colour
- 434 1/08/2004 7:34:35 PM Lawyer requested patient MRI results but did not provide patient consent for release of medical records
- 435 3/08/2004 1:58:20 PM Patient with mental illness threatened safety of GP and staff; angry as a result of being refused approval to become a school bus driver
- 436 3/08/2004 9:57:38 PM Unacceptable waiting time for specialist review of patient with PV bleeding; GP called specialist and sent to ED for review as per advice, but communication/ procedure problems btw GP, specialist and ED and patient sent home by ED due to inadequate referral letter and lack of call prior from GP
- 437 8/08/2004 11:31:23 AM Difficulty using the computer record system vaccine section due to poor setup/ user interface in this section when deviating from standard Schedule
- 438 8/08/2004 11:41:10 AM Practice nurse stocked DTPaHepB section of fridge with fluvax accidentally due to similar looking packaging

- 439 10/08/2004 9:16:51 AM Poor incision technique whilst doing wedge resection great toenail caused slip and deep cut to toe
- 440 10/08/2004 11:28:58 AM Incorrect follow-up testing of borderline GTT in pregnancy caused late detection and management of gestational diabetes
- 441 11/08/2004 8:23:53 PM Miscommunication between patient and GP regarding continuation of a medication when a script with repeats was issued caused patient to cease rather than continue
- 442 12/08/2004 12:19:22 PM Delay in diagnosis of pancreatitis as SE of Klacid; initial misdiagnosis of abdo pain as GI upset from antibiotic and treated with antiemetic; also had delayed assessment in ED of patient when presented there for assessment; both delays possible contributors to patient death from multi-organ failure
- 443 14/08/2004 1:49:46 PM Delay in home visiting patient for 2 weeks who usually has monthly home visits caused unchecked development of pulmonary oedema which required hospital admission
- 444 14/08/2004 2:00:46 PM Patient delayed consulting GP with pain symptoms because felt uncomfortable with Dr's interpersonal skills at previous visit - Dr had been "cranky"
- 445 14/08/2004 7:42:07 PM Delay in elderly patients seeking acute hospital care due to perception from TV programme that hospitals withhold treatments from elderly patients and let them die - language barriers may contribute
- 446 15/08/2004 1:37:25 PM Mistakenly gave Meningococcal C vaccine to child who had been vaccinated previously because failed to check vaccination record prior to administering it and parent unaware that she had had it, and presented requesting the vaccine
- 447 15/08/2004 4:45:14 PM Pharmacist mistakenly dispensed double strength antibiotic to child than had been prescribed
- 448 16/08/2004 10:06:42 AM Pathology sent incomplete report on results
- 449 16/08/2004 10:13:35 AM Diabetic patient sent for pathology tests and GP forgot to request HbA1c, resulting in patient requiring repeat testing sooner than usual
- 450 16/08/2004 10:32:23 AM Hospital and community nursing communication failure on patient with DVT discharge from hospital, meant nurses did not attend to give BD Clexane and patient had to present to surgery and ED over weekend for Injections
- 451 16/08/2004 6:05:54 PM GP accidentally charted incorrect ACE inhibitor medication for post AMI patient in hospital
- 452 17/08/2004 4:02:55 PM Prescription and referral letter generated on computer using incorrect patient details
- 453 18/08/2004 3:04:37 PM Nursing staff in N/Home discontinued a medication without consulting patient's GP
- 454 18/08/2004 4:45:46 PM Misdiagnosis of child sexual abuse by GPs at another practice; inappropriate management of possible child sexual abuse case by GPs at

		another practice with failure to appropriately refer to suitable place for Assessment
455	18/08/2004 5:14:55 PM	Failure to diagnose and appropriately treat/remove a FB in child's ear by GP at another practice; GP refused to listen to patient's parent who said that the child had never had grommets, and insisted FB was a grommet
456	18/08/2004 5:25:23 PM	Failure to diagnose and appropriately treat patient with acute spinal cord compression by another GP
457	22/08/2004 2:23:39 PM	Patient discharged from teaching hospital after admission for pneumonia with acute monoarthritis of ankle and no apparent assessment or treatment; GP sent patient back, and after admission for a further week patient was discharged abruptly due to bed pressures with incorrect discharge summary diagnosis, discharge summary medications, and no medication issued
458	23/08/2004 3:31:57 PM	Patient prescribed contraindicated antibiotic and had allergic reaction despite computer records
459	25/08/2004 11:50:53 AM	Failure to follow up pathology results for 3 months delayed investigation of anaemia
460	25/08/2004 11:58:54 AM	On a home visit, lowered medication strength but failed to change on computer records back at the practice, so subsequent repeat script was issued with incorrect higher dose
461	26/08/2004 4:47:40 PM	Confusion over whether 12 year old was having paediatric or adult HepB Vaccination schedule, incorrectly gave paediatric dose and required second needle; inadequate record keeping of vaccine types in notes
462	30/08/2004 10:28:22 PM	Patient left phone message with reception requesting GP to call her back, lost message with patient name and number
463	30/08/2004 10:46:38 PM	Patient unable to arrange transport to surgery from hostel delayed diagnosis of acute infected arthritis; Lack of triaging messages to GP by practice reception delayed action on charting and returning a changed medication plan for hostel patient; Hostel management failure to institute medication changes over a weekend
464	31/08/2004 11:24:19 PM	Delay in nursing staff administering charted antibiotic treatment for bacterial diarrhoea in hospital for 2 days
465	2/09/2004 6:07:16 PM	Misdiagnosis of bacterial conjunctivitis by pharmacist and delay in Appropriate treatment
466	3/09/2004 8:20:27 PM	Lack of follow up in place for abnormal PSA and glucose delayed further investigation for 6 months
467	3/09/2004 9:25:33 PM	Lack of recall in place for repeating ultrasound in patient who had had a previous orchidopexy
468	4/09/2004 8:04:36 PM	Pathology request printed with incorrect details due to generating from previous patient's computer file
469	4/09/2004 8:28:40 PM	Patient with ovarian cancer and thrombosed subclavian line commenced on warfarin prior to hospital discharge , but no appropriate follow up by GP or hospital specialist for 3 weeks resulted in INR 12 and readmission

		for IV Vit K and FFP plus multiple costly investigations
470	4/09/2004 8:40:34 PM	Mistakenly recorded pathology results in computer records of another patient of similar name and age; patient who had not had a blood test given the results of another patient by mistake
471	4/09/2004 8:48:01 PM	Accidentally wrote a script for panadeine instead of panadeine forte
472	6/09/2004 4:52:51 PM	Nurse in NH gave incorrect antibiotic, then when realised, had a delay of over 48 hours in getting and administering antibiotic treatment in patient with osteomyelitis and skin infection in a nursing home contributing to patient deterioration and death
473	6/09/2004 6:05:26 PM	Misdiagnosed and treated paraseptal cellulitis as dacryocystitis
474	6/09/2004 6:14:37 PM	Patient delayed following up abnormal pathology results with further pathology tests requested by GP investigating anaemia; Patient failed to correctly prepare for colonoscopy delaying investigation - possible dementia contributing to communication breakdown
475	7/09/2004 11:08:42 AM	GP was allowing patient to self-adjust warfarin doses and patient's INR went to 8 resulting in hospitalisation for retroperitoneal bleed
476	7/09/2004 2:35:59 PM	Failure of ED to correctly investigate and diagnose fracture in child with wrist pain, did not Xray
477	8/09/2004 4:49:46 PM	Missed diagnosing lower limb DVT
478	10/09/2004 1:28:16 PM	inadequate medical record keeping by other GP at practice
479	14/09/2004 2:24:05 PM	GP made misjudgement of patient's clinical situation and feels they incorrectly issued prescription for benzodiazepine to patient who was addicted and altered the dose on script
480	18/09/2004 9:47:26 AM	Discharged from hospital with duplicate medications in generic names, causing patient confusion
481	18/09/2004 9:51:14 AM	Warfarin commenced by specialist cardiologist without appropriate Explanation of drug risks and side effects or arranging and explaining Appropriate monitoring of INR
482	18/09/2004 7:06:33 PM	Delay in seeing patient requiring palliative care due to time pressures
483	18/09/2004 8:50:06 PM	Long delay in returning call to patient who needed phone advice on medication for cough - solo GP feeling pressured and unable to meet
484	19/09/2004 7:35:55 PM	Patient prescribed and administered antibiotic to which was allergic in Nursing Home
485	22/09/2004 10:31:55 AM	GP prescribed an ear medication that had been discontinued
486	23/09/2004 2:11:44 PM	Joint infection in hip caused by intra-articular steroid injection by Radiologist
487	27/09/2004 5:11:31 PM	GP forgot to make house call after taking message him/herself but not recording details appropriately
488	27/09/2004 5:46:00 PM	Practice equipment missing - paediatric BP cuff - impaired emergency

assessment of patient

489	28/09/2004 5:33:22 PM	Prescription written with incorrect patient name - using brother's file
490	29/09/2004 6:07:15 AM	Misdiagnosis of cerebral haemorrhage due to misinterpretation of CT results by ED doctor resulted in unnecessary cessation of warfarin
491	29/09/2004 6:28:12 AM	Patient with poor mental functioning was using two surnames at practice and so had two files both with incorrect medication summaries; medication added to regime resulted in over sedation as used the chart
492	29/09/2004 3:01:56 PM	Gave HepB vaccine 3 months early due to failure to check records prior To injection
493	29/09/2004 3:05:35 PM	Prescription generated from incorrect patient computer file, similar name
494	29/09/2004 3:08:20 PM	Prescription generated from incorrect patient computer file, similar name
495	29/09/2004 10:19:14 PM	Pharmacy dispensed medication with incorrect dosage instructions
496	30/09/2004 7:13:32 AM	Pharmacy dispensed tablet form of medication instead of SR capsule as Prescribed
497	30/09/2004 7:33:23 AM	Misfiled pathology results showing UTI in NH patient resulted in week long delay in instituting appropriate treatment
498	30/09/2004 7:44:06 AM	Patients paper based file lost in practice compromising follow-up care
499	30/09/2004 8:00:13 AM	Patient booked in for review with wrong GP by mistake, complex case, caused patient distress
500	30/09/2004 6:47:03 PM	Pneumovax given to child instead of Prevenar, other GP, unfamiliar with newer childhood vaccines, child under 5 so vaccine not recommended in this age group
501	30/09/2004 6:55:49 PM	Incorrect computer record used unknowingly by another GP seeing patient with same name
502	30/09/2004 6:59:28 PM	Incorrect DOB details recorded in patient computer file by reception staff
503	30/09/2004 7:03:54 PM	Practice nurse collected fasting bloods using incorrect collection tubes and patient had to fast again and have test repeated
504	30/09/2004 7:13:17 PM	Incorrect patient name recorded on urine specimen jar, correct name on lab request form, picked up by path lab but test had to be repeated
505	30/09/2004 9:59:17 PM	Failed to give patient results of GTT showing IGT for 2 months, lack of follow-up procedures for abnormal results
506	30/09/2004 10:56:00 PM	Accidentally gave script for Flixotide when intended Seretide due to confusion over which was combo medn, patient symptoms did not
507	30/09/2004 11:01:27 PM	Pathology courier collected incorrect blood sample from practice when GP called for urgent collection

Appendix 6: TAPS research publication describing the incidence of reported errors in general practice

This appendix contains the original research publication appearing in the *Medical Journal of Australia* in July 2006 that describes the TAPS study methodology and results relating to the quantification of the incidence of reported error in general practice.

The Threats to Australian Patient Safety (TAPS) study: incidence of reported errors in general practice

Meredith A B Makeham, Michael R Kidd, Deborah C Saltman, Michael Mira, Charles Bridges-Webb, Chris Cooper and Simone Stromer

The importance of better understanding error and safety in primary care is widely accepted, with recent calls to promote efforts and improve resources in this area of research.¹ A few studies have described errors in general practice using the incident monitoring technique,²⁻¹⁰ but none have quantified the problem.

A study of family medicine physicians in Cincinnati, USA, showed errors were identified in almost a quarter of clinical encounters.² An error rate of 75.6 per 1000 general practice appointments (7.6%) was reported in one UK study.³ Reviewing incident reports from an outpatient primary care setting, a US study reported a prevalence of adverse events of 3.7 per 100 000 clinic visits.¹¹

The Threats to Australian Patient Safety (TAPS) study is the first to estimate the incidence of errors reported by general practitioners in the community from a representative sample, and describes a new method for reporting errors using a secure web-based tool.

METHODS

Ethical approval

Approval was obtained from the University of Sydney Human Research Ethics Committee. The investigating committee was granted qualified privilege by the NSW Minister for Health, providing confidentiality of meeting minutes and protection from their use in legal actions.

Definition of error

We adopted the definition of "error" used in previous work.^{5,6,12,13} Errors may have been attributable to the reporter's actions or other unwanted occurrences:

"Errors are events in your practice that make you conclude: *That was a threat to patient wellbeing and should not happen. I don't want it to happen again.*" Such an event affects or could affect the quality of care you give your patients. Errors may be large or small, administrative or clinical, or actions taken or not taken. Errors may or may not have discernible effects. Errors in this study are

ABSTRACT

Objective: To determine the incidence of errors anonymously reported by general practitioners in NSW.

Design: The Threats to Australian Patient Safety (TAPS) study used anonymous reporting of errors by GPs via a secure web-based questionnaire for 12 months from October 2003.

Setting: General practices in NSW from three groupings: major urban centres (RRMA 1), large regional areas (RRMA 2-3), and rural and remote areas (RRMA 4-7).

Participants: 84 GPs from a stratified random sample of the population of 4666 NSW GPs — 41 (49%) from RRMA 1, 22 (26%) from RRMA 2-3, and 21 (25%) from RRMA 4-7. Participants were representative of the GP source population of 4666 doctors in NSW (Medicare items billed, participant age and sex).

Main outcome measures: Total number of error reports and incidence of reported errors per Medicare patient encounter item and per patient seen per year.

Results: 84 GPs submitted 418 error reports, claimed 490864 Medicare patient encounter items, and saw 166569 individual patients over 12 months. The incidence of reported error per Medicare patient encounter item per year was 0.078% (95% CI, 0.076%–0.080%). The incidence of reported errors per patient seen per year was 0.240% (95% CI, 0.235%–0.245%). No significant difference was seen in error reporting frequency between RRMA groupings.

Conclusions: This is the first study describing the incidence of GP-reported errors in a representative sample. When an anonymous reporting system is provided, about one error is reported for every 1000 Medicare items related to patient encounters billed, and about two errors are reported for every 1000 individual patients seen by a GP.

MJA 2006; 185: 95–98

anything that you identify as something wrong, to be avoided in the future."

Sampling method

The General Practice Programs Branch of the Commonwealth Department of Health and Ageing (GP Branch) provided a stratified random sample of 320 names from the population of 4666 vocationally registered GPs in NSW whose Medicare billings in the previous quarter indicated that they were engaged in full-time work.¹⁴

A sample size of 80 was calculated from pilot study results of 134 reports made from up to 23 GPs over 4 months, which had a 25% participation rate.⁵ Allowing 1 week of absence each and estimating 132 consultations per week,¹⁵ we hypothesised a reported error rate of 0.27% per consultation. To estimate this with a 95% confidence interval of 0.25%–0.29%, we required 205465 patient encounters. We anticipated that 80 GP participants would have about

480 000 patient encounters, with the excess allowing for any effect of clustered samples.

The sample was drawn from Rural, Remote and Metropolitan Area (RRMA) groupings of RRMA 1, RRMA 2-3, and RRMA 4-7.¹⁴ The GP Branch stratified the sample by gender and age, dichotomised around 45 years. One hundred and sixty (50%) of the sample were drawn from RRMA 1, 80 (25%) from RRMA 2-3 and 80 (25%) from RRMA 4-7 regions. The proportions of the source population in these regional groupings were 68%, 16% and 16%, respectively. The smaller groups were over-sampled to ensure adequate counts of Medicare items to allow future subgroup analysis.

A research assistant made initial contact with the GPs by telephone. If interest was expressed, an information pack was sent, followed by further telephone contact. Reasons for non-participation were recorded. All GPs who commenced the study were visited

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by a research assistant. Informed consent was obtained, the definition of "error" was explained, and a demonstration of the website to be used for reporting was given.

Anonymous online error reporting

A secure website and reporting process were developed to house the error questionnaire, shown in Box 1, which was piloted in 2001.⁵ Data transmission was protected by 128-bit encryption and the website was hosted by a secure server behind a firewall. The website allowed participants to contact investigators and view linked medical resources. Participants were asked about any website problems in monthly contact via email, telephone or facsimile.

A self-chosen Personal Identification Number (PIN) and the RRMA grouping were required to submit a report. Participants submitted a blank report before the start of the study for website testing. The participant's PINs were unknown to investigators, which protected reporter anonymity.

Comparing participants to other GPs

Total numbers of GPs, their sex and average age were obtained from the GP Branch by RRMA groupings, so that the study participants could be compared with the source population. We also compared the number of Medicare items billed relating to a patient encounter over the study duration.

Calculating the number of reported errors

Numbers of errors reported per PIN, the numbers of PINs obtained per RRMA group, and total numbers of errors from the group were obtained from website data. At the end of the study, participants were asked whether they had sent any reports electronically. To protect anonymity, we did not ask the number of reports submitted.

Calculating the incidence of reported error

Total numbers of errors from participants, counts of the number of Medicare items billed that related to a patient encounter and the number of individual patients that were seen during the study were used in incidence calculations. Patients who were seen on more than one occasion during the year by a single participant were only counted once per GP.

1 Error questionnaire used in the Threats to Australian Patient Safety (TAPS) study

Question	Answer format
a) What is the RRMA area of your practice?	RRMA 1, 2-3 or 4-7
b) Is the problem related to a specific patient?	Yes/No
c) How well do you know the patient?	5-point Likert scale
d) What is the patient's age?	Free text
e) What is the patient's sex?	Male/Female
f) Is the patient from a non-English speaking background?	Yes/No
g) Is the patient of Aboriginal or Torres Strait Islander descent?	Yes/No
h) What happened? Please consider what, where and who was involved.	Free text
i) What was the result? Please think about actual and potential consequences.	Free text
j) What may have contributed to this error? Please consider any special circumstances.	Free text
k) Where did the error happen? Choose all that apply from <i>Office or surgery, Nursing home, Hospital, Patient's home, Telephone contact, Emergency Room, Laboratory, Pharmacy, Radiology</i>	Check a box or boxes: nine choices
l) To your knowledge, was any patient harmed by this error?	Yes/No
m) If yes, how would you rate the seriousness of this harm?	5-point Likert scale
n) How often does this error occur in your practice? First time, Seldom 1-2 per year, Sometimes 3-11 per year, Frequently >1/month	Check a box: four choices
o) What could have prevented this error? Please consider what could be done to prevent similar episodes from happening in the future.	Free text
p) Other comments?	Free text

RRMA = Rural, Remote and Metropolitan Area. ♦

Data analysis

The percentage of female participants was compared with the source population using Fisher's exact test. The average participant age and number of Medicare items relating to patient encounters were compared using unpaired Student's *t* tests. A non-parametric method adjusting for clustering was used to compare the median number of reports per PIN. Incidence calculations included sampling weights for the three RRMA groupings to adjust for the relative over-sampling of RRMA 2-3 and RRMA 4-7 GPs. All statistical analysis was performed using Stata 8.0 software (StataCorp, College Station, Tex, USA).

RESULTS

Participants

From the initial sample of 320, we were unable to contact 52 GPs (16.3%) who had moved away, retired, or were completely unknown to the practice. A further 43 GPs (13.4%) did not return researchers' calls or gave no specific reason for declining. Of those remaining, 91 (40.4%) were too busy or not interested, 20 (8.9%) had difficulties

with computer use or access, 18 (8.0%) were retiring or taking extended leave during the study, eight (3.6%) did not participate in research, three (1.3%) had concerns about privacy, and one (0.4%) had concerns about bad publicity. There were 84 GPs (26.3% of the original sample) who agreed to commence the study, with 41 from RRMA 1, 22 from RRMA 2-3, and 21 from RRMA 4-7 regions. One RRMA 1 GP and one RRMA 4-7 GP left the study. As reporting was anonymous, their results were included in further calculations.

Comparing participants with other GPs

The participants' average age, percentage of female GPs, and average number of Medicare patient encounter items were assessed. There was no difference in comparison to the source population within each RRMA grouping, or for all combined, using any of these measures at the 5% significance level.

Number of error reports submitted

There were 418 TAPS reports from 85 PINs describing an error during the study. The mean number of error reports per month

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was 34.8 (range, 15–60). At feedback interview, 79 of the 82 completing participants had submitted a report.

Box 2 shows RRMA grouping comparisons of the number of reports submitted, PINs submitted, GPs who reported at interview sending a report, average number of reports per GP and the median number of reports per PIN over the study period.

Frequency of error reporting

The distribution of reporting frequencies among RRMA groupings was assessed by looking at the number of reports per PIN, shown in Box 3. This varied from one to 25, with a median of three for all participants combined. There was no significant difference between RRMA groupings in the median number of reports submitted per PIN ($P = 0.40$) (for this analysis, values that were equal to the median were evenly split between the above and below groups).

Incidence of reported error

The total numbers of Medicare items relating to a patient encounter and total numbers of individual patients seen by RRMA grouping are shown in Box 4. Each report within an RRMA grouping was matched with the group's average number of Medicare items and average number of patients seen, and assigned a sampling weight to adjust for the larger representation of RRMA 2–3 and RRMA 4–7 GPs in the sample design.

The resulting calculations gave an incidence of anonymously reported errors per Medicare patient encounter item per year of 0.078% (95% CI, 0.076%–0.080%), and an incidence of reported errors per patient seen per year of 0.240% (95% CI, 0.235%–0.245%).

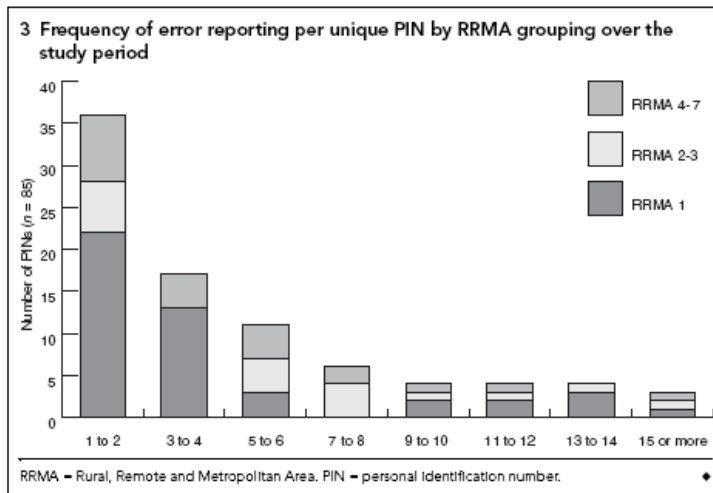
DISCUSSION

Original research on errors and adverse events in primary care consists of relatively limited numbers of studies, focusing on qualitative descriptions.¹⁶ The TAPS study provides the first calculated incidence of reported error from a representative random sample of GPs. Despite the small sample size and participation rate of 26%, these findings are likely to be generalisable to GPs in NSW, as we detected no statistically significant differences between the age, sex, and Medicare billings when comparing participants to the source population of 4666 GPs. Comparative data were not available from the GP Branch for the non-participants due to consent issues.

2 Summary statistics describing TAPS reports submitted by RRMA group over the study period

RRMA group	Number of participants	TAPS reports received	Unique PINs submitted	Number of GPs who sent a report *	Average reports per GP	Median reports per unique PIN
1	41	199	46	38	5.2	3
2–3	22	121	18	21	5.8	6
4–7	21	98	21	20	4.9	4
Total	84	418	85	79	5.3	3

*According to feedback provided at interview. TAPS = Threats to Australian Patient Safety. RRMA = Rural, Remote and Metropolitan Area. PIN = personal identification number.



We conclude from our incidence findings that, when an anonymous and simple reporting system is provided, about one error is reported for every 1000 Medicare items related to patient encounters billed per year, and about two errors are reported for every 1000 individual patients seen by a GP per year.

It has been suggested previously that an error database in general practice should be established.^{17,18} Our results indicate that using a secure website with an anonymous reporting method is a practical way of collecting error information from GPs, as 94% of doctors who enrolled in the study reported at interview that they sent an error report.

Our findings provide an estimation of the incidence of errors in general practice that would be reported if an appropriate reporting system were in place, but this should not be interpreted as an estimate of the total number of errors that participants noticed,

or of the underlying number of errors occurring in the GP community. It is very difficult to assess the proportion of errors that would go unreported even when a reporting system such as TAPS is available. A GP may not be aware that an error has occurred. GPs have been found to under-report adverse drug events,¹⁹ and so other patient safety threats may also be under-reported.

4 The number of Medicare items relating to a patient encounter and individual patients seen by participants during the study

	RRMA 1	RRMA 2–3	RRMA 4–7	All RRMA
Medicare Items	260150	127610	103104	490864
Patients seen	89042	45176	32351	166569

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Anonymity was of major importance in our methodological design, to encourage reporting. There has previously been a reluctance of health professionals to address the problem of errors due to feelings of guilt and a desire to avoid disapproval from colleagues.²⁰ However, using a PIN that was unknown to investigators led to some difficulties in interpreting reports per GP. Researchers were unable to assist if a PIN was forgotten, and there was no way of knowing how many GPs changed PINs during the study. Seventy-nine GPs gave feedback that they submitted an error report, but 85 PINs were used for error reports, which suggests that on at least six occasions GPs changed their PINs. Our estimate of report numbers per participant, which is based on PINs, could therefore be an underestimate.

The number of individual Medicare items billed relating to a patient encounter is the best approximation that we could make of separate consultations, but should not be interpreted directly as such. A GP may claim more than one Medicare item from a single encounter, which is not revealed in our data. Consultations may also have occurred which were not billed, charged to the patient privately, or charged to the Department of Veterans' Affairs, which keeps separate data from the GP Branch.

To our knowledge, there are no studies directly comparable with our incidence results, which are lower than hypothesised. The authors of a US study that found an error rate close to 25% state that their results were not generalisable due to limitations of the study.² Only a small group of 15 doctors in seven practices made reports, completing a review form after every consultation during three half-day sessions. The UK finding of a 7.6% error rate was based on a 2-week collection of errors from 10 practices in a single city.³ However, a major difference is that this result was based upon a collection of reports from a large cross-section of staff working in general practice, with 163 people able to submit reports, and a high proportion of participants who had administrative rather than clinical roles.

Our method of prospective self-reporting appears to have returned a higher rate of error detection than that in a US study using retrospective record review in eight primary health care clinics.¹¹ Again, direct comparison is difficult, as medical adverse events were counted in this work, rather than errors in the sense that we defined.

In considering the adoption of a method of error reporting for primary care, retrospective record review lacks potential for use as an active learning tool. A prospective electronic reporting tool could be enhanced with the addition of feedback to the user and links to educational activities, plus have the scope to allow many other stakeholders in primary care settings to contribute error information.

The TAPS study improves our current understanding of the incidence of reporting threats to patient safety in general practice, and its method provides a way for GPs to discuss errors in a non-threatening environment.

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COMPETING INTERESTS

None declared.

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Appendix 7: TAPS research publication describing a new taxonomy for general practice patient safety event reporting and proportions of error types

This appendix contains the original research publication in the journal *Quality and Safety in Health Care* of the article ‘Patient safety events reported in general practice: a taxonomy’, which details the development and end result of the creation of the TAPS taxonomy, and the proportions of errors by type that occurred in the TAPS data set.

IN PRESS, Accepted for publication 15th June 2007

PATIENT SAFETY EVENTS REPORTED IN GENERAL PRACTICE:
A TAXONOMY

Word count: 1991

Number of Figures: 2 (boxes)

Number of Tables: 3

Abbreviated Title: Types of patient safety events reported in General Practice

Indexing Terms: Patient safety events, medical errors, critical incidents, adverse events, General Practice, Family Practice, error reporting, incident monitoring, taxonomy, classification, coding

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ABSTRACT

Objective

To develop a taxonomy describing patient safety events in General Practice from reports submitted by a random representative sample of General Practitioners (GPs), and to determine proportions of reported event types.

Design

433 reports received by the Threats to Australian Patient Safety (TAPS) study were analysed by three investigating GPs, classifying event types contained. Agreement between investigators was recorded as the taxonomy developed.

Setting and Participants

84 volunteers from a random sample of 320 GPs, previously shown to be representative of 4666 GPs in NSW, Australia.

Main Outcome Measures

Taxonomy, agreement of investigators coding, proportions of error types.

Results

A three level taxonomy resulted. At the first level, errors relating to the processes of health care (type 1) were more common than those relating to deficiencies in the knowledge and skills of health professionals (type 2) at 69% and 31% respectively. At the second level, five type 1 themes were identified: Health care systems (21%); investigations (12%); medications (20%); other treatments (3%); and communication (13%). Two type 2 themes were identified: Diagnosis (12%) and management (19%). Level three comprised 35 descriptors of the themes. Good inter-coder agreement was demonstrated with an overall kappa score of 0.66. A least two out of three investigators independently agreed on event classification in 92% of cases.

Conclusions

The proposed taxonomy for reported events in General Practice provides a comprehensible tool for clinicians describing threats to patient safety, and could be built into reporting systems to remove difficulties arising from coder interpretation of events.

Abstract word count = 250

INTRODUCTION

There is little information available on the proportions of types of patient safety events that are reported in General Practice settings, and no taxonomy that is widely used by General Practitioners (GPs) to describe these events.

Previous studies in primary care have provided descriptions of the relative proportions of different types of patient safety events that they have collected,[1-10] but none have been based upon a representative sample of primary care clinicians contributing data, and all have used different classification methods.

In recent years, a small number of taxonomies of patient safety events related to a General Practice setting have been proposed,[7, 11-13] all based upon patient safety event reports collected from small non-random samples of participants. They use both causative and descriptive elements of like themes to group events, sometimes referred to as ‘domain specific’ taxonomies.[14]

‘Multiaxial taxonomies’ capture additional elements of an event, such as harm levels, location, participants or preventability. One study has developed such a tool in a primary care setting in North America,[15, 16] although its full details have not been published in the scientific literature, and another has been suggested as one that could allow comparison of safety events across disciplines, although no trial of it in a primary care setting has been described.[17]

There have also been some recent calls for classifications that address cognitive psychological processes,[18] with one developed for general practice,[14] also yet to be tested. Finally, one taxonomy has been described that is based upon patients’ perceptions of harms in primary care, although it has a limited application in terms of categorizing causes of events.[19]

The Threats to Australian Patient Safety (TAPS) study estimated the incidence of General Practitioner (GP) reported patient safety events in the community, using a method based upon a randomly selected representative sample of GPs.[20] We found that limitations mainly relating to the internal validity of existing tools warranted further taxonomy development. We aimed to develop a taxonomy that would be

comprehensible and practical for primary care clinicians to apply themselves, and we describe the first attempts to validate a taxonomy in terms of its reproducibility with GPs.

METHODS

The methods and definitions used in the TAPS study have been previously described, with 84 GPs in NSW anonymously reporting 'errors' (patient safety events) that they noted in their daily practice (including ambulatory clinics, hospital settings and residential aged care facilities) for a twelve month period via a secure on-line questionnaire.[20] Approval for the study was obtained from the University of Sydney Human Research and Evaluation Ethics Committee.

TAPS Taxonomy development

Three GPs from the investigating team (MAM, SS and CBW) classified each report using an existing pilot taxonomy,[12] and results were compared to obtain a baseline measure of reproducibility. Reports containing more than one event were given multiple codes in chronological order of events. A report required two out of three reviewers in agreement to be assigned a classification. Where three different codes had been assigned, the report was reviewed at a face to face meeting to determine its classification. The initial taxonomy was amended and retested using one quarter of the reports each time, over four sessions, to produce the TAPS taxonomy. A set of guidelines to improve coder consistency when using the taxonomy was also developed.

Agreement of investigators developing the taxonomy

Concordance amongst the coders was measured using the kappa statistic, for both the initial taxonomy and the final TAPS taxonomy. Only one classification per report was included for the kappa score calculations. If reports were assigned multiple classifications by one or more coders, the first classification most commonly assigned was included. The kappa statistic can range from -1 (perfect disagreement) to +1 (perfect agreement). A kappa score of between 0.40 and 0.75 indicates fair agreement.[21, 22] All statistical analysis was performed using Stata 8.0 software.[23]

RESULTS

Patient safety event numbers

433 website submissions were received, with 415 containing true reports after discounting tests and reports with missing data (15), and reports that investigators deemed to have no patient safety event described within them (3). Of the remaining 415 reports, 320 contained one event, 82 contained two events, 11 contained three events, and 2 contained 4 events.

The TAPS taxonomy

The resulting taxonomy has 3 levels of classification. The first level ('event type') relates to the underlying cause of the event, being either due to deficiencies in the process of delivering health care (type 1), or the knowledge and skills of health professionals (type 2). The second level has five groupings ('themes') within type 1 errors, and two groupings within type 2 errors. The themes within type 1 are practice and health care systems, investigations, medications, non-medication treatments and communication. The type 2 themes are diagnosis and managing patient care. At the third level there are from 3 to 9 'descriptors' per theme. .

Table 1 shows raw counts and proportions of total events for each category of the taxonomy. The guidelines for using the taxonomy is shown in table 2. Examples of reports describing type 1 versus type 2 events are shown in boxes 1 and 2, with the codes used to describe them.

Table 1. TAPS taxonomy with results of 525 patient safety events within 415 reports.

N	% of total	
365	69.5	1. Errors related to the Processes of Health Care
112	21.3	1.1. Errors in practice and health care systems
12	2.3	1.1.1 Errors relating to incorrect patient identification
15	2.9	1.1.2 Appointments and message handling errors
28	5.3	1.1.3 Patient record and filing system errors
25	4.8	1.1.4 Recall event and recall systems errors
6	1.1	1.1.5 Computer systems errors
6	1.1	1.1.6 Errors in the maintenance of a safe physical environment
7	1.3	1.1.7 Errors in provision of care after hours or inadequate staff coverage
3	0.6	1.1.8 Errors relating to patient confidentiality issues
10	1.9	1.1.9 Practice and health care systems errors not otherwise specified
65	12.4	1.2. Investigation errors
7	1.3	1.2.1 Errors relating to incorrect patient identification
12	2.3	1.2.2 Errors in the process of requesting investigations
9	1.7	1.2.3 Errors in the process of undertaking investigations
35	6.7	1.2.4 Errors in reporting processes or managing investigation reports
2	0.4	1.2.5 Investigation errors not otherwise specified
107	20.4	1.3. Medication errors
31	5.9	1.3.1. Electronic prescription writing or medication charting errors
16	3.1	1.3.2 Other prescription or medication charting errors
38	7.2	1.3.3 Medication dispensing and delivery errors
11	2.1	1.3.4 Patient self-administration of medication errors
11	2.1	1.3.5 Medication errors not otherwise specified
13	2.5	1.4. Treatment errors (non-medication)
11	2.1	1.4.1 Errors in the process of providing Immunisations
1	0.2	1.4.2. Errors in the process of undertaking procedures
1	0.2	1.4.3. Non-medication treatment errors not otherwise specified
68	12.9	1.5. Communication errors and process errors not otherwise specified
17	3.2	1.5.1. Errors in general communication with patients
31	5.9	1.5.2 Hospital discharge and other hospital based communication errors
9	1.7	1.5.3. Errors in referral to other health care providers
8	1.5	1.5.4 Errors in general communication with other health care providers
3	0.6	1.5.5. Communication and process errors not otherwise specified
160	30.5	2. Errors related to the Knowledge and Skills of Health Professionals
62	11.8	2.1. Errors in diagnosis
2	0.4	2.1.1. Errors in patient history taking
11	2.1	2.1.2. Errors in patient physical examination
27	5.1	2.1.3. Errors in investigations requested or their interpretation
22	4.2	2.1.4. Diagnosis related errors <i>not otherwise specified</i>
98	18.7	2.2. Errors in managing patient care
57	10.9	2.2.1 Medication management errors
9	1.7	2.2.2 Knowledge or skills errors in undertaking immunisations
13	2.5	2.2.3 Knowledge or skills errors in undertaking procedures
19	3.6	2.2.4 Errors managing care not otherwise specified

Table 2. TAPS taxonomy guidelines for coding patient safety events.

TAPS taxonomy guidelines for use	
5.	Consider the number of ‘patient safety events’ or separate elements that have contributed to a report describing a threat to patient safety, and classify each distinct patient safety event separately if there are more than one.
6.	Consider the underlying cause to first code the event ‘type’ . Consider whether it should be considered as resulting from a breakdown in the ‘processes’ around patient care (type 1), or in the knowledge or skills base required for any person involved in the delivery of patient care (type 2).
7.	Next assign the second level ‘theme’ of the patient safety event, choosing the most specific option from those listed within the assigned event type. (that is, from 1.1 to 1.5 for ‘type 1’ events, or 2.1 to 2.2 for ‘type 2’ events). <i>*For type 1 events, use theme 1.5 ‘Communication errors and process errors not otherwise specified’ when a more specific theme is not suitable.</i>
8.	To complete, assign the most specific level 3 ‘descriptor’ available from within the second level theme chosen. In general, these descriptors are listed from more specific to less specific when moving down the list.

Box 1. TAPS case study of a report containing a patient safety event relating to the processes of health care.

A patient of a general practice with a background of developmental delay, epilepsy and schizophrenia attended regularly but used two different surnames on different occasions, being both those of his divorced parents. The practice mistakenly held two different electronic records for him under these two names, which contained different medication lists. He was prescribed a new medication which resulted in him becoming over-sedated, lethargic and depressed as a result of an interaction with a medication listed in the other chart, before the mistake was discovered.

TAPS Code 113
Type Processes of health care
Theme Errors in practice and health care systems
Descriptor Patient record and filing system errors

Box 2. TAPS case study of a report containing patient safety events relating to the knowledge and skills of health professionals.

A patient with severe depression was scheduled by their General Practitioner (GP) to the regional psychiatric hospital. A week later he returned to the GP for follow-up after discharge. The patient reported to the GP that he had complained of increasing pain in the chest after admission to the psychiatric unit, and after some delay he was sent into the base hospital by the psychiatric unit for a chest Xray without actually being physically examined. The chest Xray was normal, and after a further 3 days he was examined by a medical officer in the psychiatric unit and found to have a florid shingles rash. He was eventually sent home on analgesia, but antiviral management had not been appropriately instituted.

TAPS Code	212, 221 (2 events identified)
Type	Knowledge and skills of health professionals (both events)
Theme	Errors in diagnosis (event 1) Errors in managing patient care (event 2)
Descriptor	Errors in patient physical examination (event 1) Medication management errors (event 2)

Coder agreement from pilot to TAPS taxonomy

The investigators coded the set of 433 reports using the pilot taxonomy,[12] and the final 132 reports (approximately one quarter) were coded using the TAPS taxonomy. The agreement amongst the three coders at each level of both the pilot and TAPS taxonomies, with corresponding kappa scores, are shown in table 3. At the third level of the code from the pilot to the TAPS taxonomy, the proportion of reports in which at least two of three coders agreed rose from 74% to 92%, and the kappa score moved from 0.37 to 0.66.

Table 3. The proportion of agreement amongst the three coders and kappa score at each level of the taxonomies, comparing the pilot to the TAPS taxonomy.

Coding level	Taxonomy	Complete disagreement %	Two of three coders agree %	Complete agreement %	Kappa score
Level 1 (Type)	<i>Pilot</i>	2	28	70	0.59
	<i>TAPS</i>	0	10	90	0.82
Level 2 (Theme)	<i>Pilot</i>	14	45	41	0.48
	<i>TAPS</i>	1	34	65	0.72
Level 3 (Descriptor)	<i>Pilot</i>	26	49	25	0.37
	<i>TAPS</i>	8	34	58	0.66

DISCUSSION

Our proposed taxonomy builds upon pilot work which has at its primary level a causative classification,[11, 12] adding sub-categories to this by grouping like themes, and then adding detail with descriptive categories in the style of a domain specific taxonomy. Application of the taxonomy to the TAPS data shows that the majority of reports contained a single patient safety event, and the majority of events related to the processes of providing health care rather than deficiencies in knowledge and skills of health professionals, as postulated in previous work with non-representative samples.[7, 9, 11, 12]

The reporting GPs demonstrated a clear understanding of the definition of error used. [20] Investigators found less than 1% of reports to contain no safety event. The proposed seven themes adequately described all reported events. The addition of “not otherwise specified” as a descriptor for each theme, unlike previous similar taxonomies, [5-7] allowed complete event coding, incorporating 13% of classified events. This compares with 2.2% of reports in one single level UK taxonomy, [2] although it provided no other detail on the error type, and 20% of the ‘cause’ of anonymous reports using a multiaxial taxonomy in one study from the United States. [3]

The largest proportion of events were classified as relating to ‘practice and health care systems’ at the theme level (21%), consistent with American and UK studies,[7, 11] although our category is different from any in previously described taxonomies as it contains elements of the larger health care system rather than just ‘administrative’ events. The 2002 pilot study had found a similar proportion of ‘office administration’ events (20%).[12]

If both types 1 and 2 events are combined, ‘medication’ errors represent the largest proportion (31%), similar to findings in earlier Australian work.[3, 4] The TAPS taxonomy allows the cause of medication errors to be considered, whether related to knowledge of their use (events 2.2.1), or to systems problems in their provision (events 1.3.1 to 1.3.5). This may assist in planning prevention measures, such as education for clinicians or systems changes that would reduce electronic prescription errors or dispensing mistakes.

Our purpose was to develop a tool that would be comprehensible to primary care clinicians reporting safety events. The use of investigators with a clinical background in General Practice was important to produce language that would be acceptable for self-coding. One other study has asked the reporting clinicians to code the events using a simple descriptive taxonomy.[7] However, the study period was brief, and the majority of reporters were reception staff, so some event types may not have been captured.

There are no studies with which we can compare our results on reproducibility of the taxonomy. The kappa statistic and proportions in table 3 showed a marked improvement in agreement from the pilot to the TAPS taxonomy at all levels of the code. It is possible that a degree of improvement could have occurred through an unconscious learning of each others styles at the taxonomy development meetings, in addition to improved clarity of the code itself. As expected, there was less agreement amongst coders comparing level 1 to 2, and level 2 to 3, due to more coding choices.

At the most detailed third level of the taxonomies, complete disagreement amongst the coders fell from over a quarter to less than ten per cent of cases. In the cases

where complete agreement was not reached, there was often a difficulty in interpreting the reporting language used, or a brevity of description provided in the report, requiring a degree of personal interpretation or assumption from the coding GPs. While further refinement of the taxonomy might lessen possible ambiguity, we believe that a system where the reporting clinician actually codes the event would reduce this type of error by eliminating a loss of detail in the process of describing the event and its cause to another clinician or analyst conducting the coding.

The taxonomy developed by the Applied Strategies for Improving Patient Safety (ASIPS) collaborative[15, 16] is a multiaxial model developed in a primary care setting, using trained analysts to classify reported events. It has not been published in the peer-reviewed literature in full, however it is able to be viewed online.[24] The TAPS electronic reporting system collects data of a similar nature to the additional axes and domains of ASIPS, including a harm scale, location check-box, event frequency scale, and details of patients such as age, gender and ethnicity.[20] These elements are closed questions completed electronically by the reporter. They could be combined with reporters self-coding an event with the TAPS taxonomy to effectively produce a self-reported multiaxial taxonomy describing safety events.

An important limitation of our results is that they do not represent the underlying proportions of error types in the community, although the reporters were a representative sample. Some event types may have been under-reported in comparison to others, despite efforts to encourage reporting. Participants may have been unaware of deficits in their own knowledge or skills.

The TAPS reports are a reflection of GP's experiences, and the taxonomy was created by GPs. As such, it may be limited in its application to other primary care groups. In other studies, a variety of clinicians or administrative staff have been required to report events,[6, 7, 14-16, 25-27] and it would be important to explore language differences that may exist.

The TAPS reports and taxonomy may not have captured all error types that could be reported by a more diverse group. One other General Practice taxonomy has recently been shown to be acceptable to opticians reporting safety events [33]. The TAPS

taxonomy may similarly have potential uses to other disciplines in a community setting.

Our purpose in this paper did not include an appraisal of error types in relation to harm, preventability and demographics of patients affected by threats to safety, however this analysis is underway.

We believe that the TAPS taxonomy has the potential for use as part of an anonymous national electronic reporting system, and offers guidance to policy makers in directing efforts to reduce patient safety threats in the community, particularly at a systems level. Further application of the TAPS taxonomy may also aid professional bodies developing educational tools aimed at improving the knowledge and skills of providers in primary care.

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COMPETING INTERESTS

None identified.

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Appendix 8: Literature review invited by saferhealthcare.org.uk, website of the BMJ/National Patient Safety Agency, UK.

This appendix shows the commissioned article for the BMJ/National Patient Safety Agency website www.saferhealthcare.org.uk.

This article is in the style of a ‘What we know’ article, which is a peer reviewed, 2000 word piece, entitled ‘Monitoring threats to patient safety in community settings: a review of the literature.’

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INTRODUCTION

The study of patient safety in community settings is recognized as a relatively under-researched area. A stronger emphasis on community based patient safety research is important because the overwhelming majority of healthcare is delivered outside hospitals, in community settings [1].

The types of threats to patient safety in community settings are often distinctly different from hospital settings due to factors such as the nature of clinical presentations, and the health care delivery environment. Community care is often more logistically complex than hospital-based care. More than one site (not necessarily designed for providing healthcare) is often involved in an episode of care and this has implications for failures in communication, patient and information transfer.

Promoting the ‘safety culture’ has been recognized as a key factor in enhancing patient safety in primary care. Patient safety may be improved through the cultural change associated with an increased sensitivity to safety issues when sentinel event monitoring systems are established [2] [3].

This review examines the peer reviewed scientific literature about patient safety event reporting and the measurement of threats to patient safety in community settings, including the methods that have been applied to collect information relating to safety events, the measurement and classification methods that have been used to describe these events, and design features of patient safety event reporting systems in the community.

LITERATURE REVIEW METHODS

A comprehensive review of the published scientific literature was undertaken using OVID Medline 1966 – present. A variety of Medical Subject Headings (MeSH terms) relating to patient safety, primary care and incident reporting were used, and additional searches of the Web of Science (general and related references) and Excerpta Medica (EMBASE) were undertaken. The reference lists of selected articles

were scanned for any additional publications. Literature limited to specific types of event reporting such as systems for adverse drug reactions was not included.

KEY MESSAGES

The key messages from this review are shown in box 1.

Box 1: Key messages in this literature review.

- Incident reporting systems are reported as the method most often applied to safety event data collection in community settings
- Incident reporting systems have been trialled and are acceptable to primary care providers, however the National Reporting and Learning System established by the National Patient Safety Agency in the UK is the only national safety event reporting system reported in the literature as being an anonymous secure system accessible to health care workers in community settings
- There is a large variation in definitions of ‘error’ and other related terms in patient safety research, and national or preferably international uniformity should be established to improve shared understanding of the subject
- Taxonomies of patient safety events in community settings are of two main types: ‘domain specific’ and ‘multiaxial’, and the appropriate classification will depend on the aims of the research, nature of the reporters and resources available to analyse data
- Despite a recognized poor ‘safety culture’ in primary health care, clinician attitudes to safety event reporting are positive provided the reporting systems are non-punitive, educational, and support clinical care

MONITORING SAFETY IN THE COMMUNITY: METHODS

Definitions

There is no single definition that conveys the accepted meaning of what should define a patient safety event in a community setting. The literature on patient safety in community settings has used a range of definitions of error, around the notion of whether or not the reporter of an event should base their inclusion of the incident on whether or not a patient may have been harmed, or potentially harmed. Various

researchers and organizations in the field have produced documents suggesting preferred definitions [4, 5], and shared concepts and standard definitions are a necessary concept for the field of patient safety to progress [6].

Research Questions

The specific type of research question being considered in a study is the most important factor in determining an appropriate methodology. In the literature studying patient safety in community settings, the research questions fell into the groups shown in box 2:

Box 2. Research questions posed in patient safety literature in community settings.

- What are the types of patient safety events occurring?
- What is the prevalence of patient safety event types occurring?
- What are the design features of a community based patient safety event reporting system?
- What are the attitudes to reporting community based patient safety events?

Data collection methods

Methods used in studies in community settings that monitor patient safety events have predominantly used prospective event reporting, with survey designs ('incident reporting systems') [7-19]. A small number of studies have used other methods including interviews with health care providers [20, 21], reviews of incident reports or malpractice claims data [22, 23], and interviewing primary care patients [24]. Unlike hospital based studies, no studies in community settings using direct observation of incidents, review of medical records, or autopsy reports were found in the literature.

MONITORING SAFETY IN THE COMMUNITY: MEASURES

Only seven groups of studies that propose a measure (or taxonomy) for describing safety events in the primary care setting were identified in the literature [11, 12, 15-17, 24, 25]. These classifications fell into two main categories: (1) 'multiaxial' taxonomies and (2) 'domain specific' or more simple classifications describing a single element of the safety event [25]. The former incorporate a number of different aspects about a safety event into its coding, such as the nature of the event, associated

harm, patient and reporter factors, or cognitive factors in its causation. The identified domain specific taxonomies focus mainly on the nature of the event in categories with a mixture of clinical and administrative titles.

Box 3. Features of patient safety events described by taxonomies developed in community settings.

- Nature or descriptive type of event
- Location of event
- Mitigating factors associated with events
- Outcomes of event, including patient harm
- Patient factors, such as age, gender and ethnicity
- Reporter factors, such as profession
- Preventative factors relating to events

Multi-axial taxonomies

The taxonomy used by the Applied Strategies for Improving Patient Safety (ASIPS) collaborative in the United States (USA), is an example of this category of measures [15]. These are appropriate tools if the research question requires a detailed measure of a safety event at multiple levels, as when the research attempts to address the complexity of the underlying causation and associated features of specific event types. This process is carried out by specifically trained coders and analysts, following notification of a patient safety event by a healthcare provider or patient. Other multi-axial taxonomies may also be appropriate for community based settings but have not yet been field tested. An example is the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Patient Safety Event Taxonomy [26].

Domain specific taxonomies

These most commonly describe ‘event type’ without necessarily incorporating a measurement of other aspects of the event such as location, provider, and associated harm. Due to their simplicity, they may be more practicable for broad application in community settings. They could appropriately address questions about the types of patient safety risks occurring in community based settings, and their quantification. A less complex taxonomy, such as described in the literature relating to the Preliminary

Taxonomy of Medical Errors in Primary Care [11], the simplified three level taxonomy from the International Study of Medical Errors [12], or the taxonomy developed in a United Kingdom (UK) general practice study [17], could be tools that providers of community based care access to code event types themselves. An electronic event reporting system may also capture patient safety domains other than the causal and descriptive factors (such as a severity score, location, patient demographic factors, or reporter factors), which could be combined with a descriptive taxonomy to answer other questions about factors associated with specific event types.

Limitations of taxonomies described

Not all of the taxonomies in the literature proposed for community settings have been tested, and in those that have, there are major limitations to consider with respect to their validity and comprehensibility. None of the studies attempted to test the reproducibility of their proposed taxonomies across different analysts or primary care clinicians. Of all the studies identified discussing safety events in community settings, only one used a representative sample [19]. Although a taxonomy developed to cross disciplines has been proposed [26], it also remains untested in primary care.

MONITORING SAFETY IN THE COMMUNITY: CURRENT FINDINGS

Types of patient safety events

Incident reporting systems are most commonly used to answer questions relating to types of safety events. There were variations in the style by which reports were collected, including completing a paper based proforma or questionnaire[7, 10, 16, 17], telephone reporting[18], electronic transmission of reports[12], secure web-based reports[8, 9, 19], or a combination of these[11, 13-15]. Reporter protections varied, with clinicians being anonymous[12, 19], reporting confidentially[7, 10, 25], being identified[16, 17], or a combination or option of these[13-15]. Some settings had varying legal protections in place to prevent litigation[7, 10, 18]. The profession of reporters also varied, so that some collections of data were by general practitioners or family physicians only[7, 10-12, 16, 19], while other studies used a variety of other community based medical, allied health, nursing, administrative and reception staff [13-15, 17, 18]. In addition to varying types of participants in these studies and their reporting options and protections, a variety of both definitions of reportable events

and classification systems used to describe events make the results of these studies difficult to combine or compare.

Prevalence of safety events

The results of studies asking questions about the prevalence of safety events using incident reporting were limited by the fact that reporters may not recognize safety events, or choose to report for a variety of reasons. One Australian study used a representative random sample of General Practitioners and counted their consultations with patients over a twelve month period. It was found that if an anonymous, secure, web-based reporting system was provided, approximately 2 errors were reported per 1000 patients seen per year [19]. A review of a large US malpractice database over a five year period found that problems with high severity outcomes and death more often involved claims with communication between providers and early hospital discharge as contributing factors [23], however malpractice data represent a limited view of patient safety events, missing many episodes that have no association with insurance companies.

Design features of safety event reporting systems

Evidence of the design success of a system should be considered in terms of its ability to answer the research questions that it set out to address, or provide the service or education to clinicians for whom it was established. To date there is little critical appraisal of existing reporting systems along these lines, and further evidence is needed before one particular style of reporting model should clearly be supported over another.

A non-punitive approach to safety event reporting has been supported in the literature [27, 28]. A Danish survey of 1200 General Practitioners showed that they had a positive attitude towards reporting adverse events to a database if the system granted legal and administrative immunity to reporters [27].

There is some debate over the benefit of a legally protected and confidential method versus an anonymous approach to reporting, with some advocating confidential reporting provides more detailed data and opportunities to further explore safety events [14]. However the anonymous approach has been used in several studies and

is more likely to prevent unwanted discovery of reporter details. To date, no reports of a legal challenge associated with a patient safety event reporting system in primary care have been found, so confidential systems are untested with respect to protecting reporters from legal action.

MONITORING SAFETY IN THE COMMUNITY: FUTURE DIRECTIONS

Patient safety event reporting in community settings is a relatively new activity, and much more research is required to refine and test the reliability and validity of the methods and measures described in this review. We recommend this as a priority for patient safety advancement. Recent discussion in the scientific literature has postulated that the gap in knowledge around the rarely researched subject of patient error may be an important source of threat to patient safety [29]. Uniformity in definitions, a clear sense of the research questions being posed and other aims of a safety event reporting system (such as educational goals) should be clearly identified by researchers, and the use of guides such as those created by the WHO World Alliance for Patient Safety is recommended.

SUMMARY

National patient safety event reporting systems have been established in mainly hospital settings in several countries, including the Czech Republic, Denmark, the Netherlands, Ireland, Slovenia, and Sweden [30]. Only the National Reporting and Learning System of England and Wales is reported in the scientific literature as readily accessible to all clinicians in the community setting via an anonymous secure website. Overviews of its results have been published, however there have been no specifics of its findings in the community setting published so far [8, 9].

Incident reporting systems are reported as the method most often applied to safety event data collection in the community setting, but large variation in definitions of ‘error’ and other related terms in patient safety research limit attempts to combine the findings of these studies. Taxonomies of patient safety events in community settings are mainly in developmental stages, and much further testing is required in the field. Community based clinician attitudes to safety event reporting are generally positive, provided the systems in place are non-punitive and educational, and their institution

on large scales would likely provide a mechanism to assist in improving the safety culture in community settings.

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Appendix 9: Letter to Australian Family Physician arising from TAPS immunisation error

This appendix is the text of a letter to the editor that was published in *Australian Family Physician* in September 2004. It highlights the recurring error that was noted in relation to reconstituting the Meningococcal Group C vaccine, Menjugate, in the form that had been previously distributed by the state health department of NSW to many practices, presented in ten vial packs.

To the Editor:

The Threats to Australian Patient Safety (TAPS) Project is an NHMRC funded study, in which General Practitioners make anonymous reports using a highly secure website concerning error events that they note in their daily practice.

Data collection commenced in October 2003 with 84 participants spread across metropolitan, regional and rural NSW. The methodology is based upon a pilot study involving six countries (1).

A repeated error posing a significant potential safety threat was found to have occurred in the first quarter of data collection related to the administration of a type of Meningococcal Group C vaccine, Menjugate ten (10) vial packs. The package contains five vials of powder and separate five vials of solvent. Reports have been received of practice staff opening these packs, selecting the solvent vial and injecting it, only later to discover that there are one or more unused vials of vaccine powder left in the box. We are unaware of any case reports of vaccine failure due to this problem.

As a result of the TAPS reports, CSL Pharmaceutical Group was notified about this potential problem via the Quality Care National Standing Committee of the RACGP, and responded by indicating that they would distribute an information leaflet outlining the optimum method of preparing the vaccine.

The packaging in question was discontinued in June 2003, and Menjugate has since been supplied in Australia as a unit dose presentation with the solvent and vaccine paired. However, the existing stocks of the Menjugate ten vial pack may take some time to be used and replaced in the community, posing a significant public health issue as the implication of inadequate coverage for patients is life threatening. In addition, practitioners may wish to review the records of those patients who have received this vaccination and ensure that it was given correctly if the serial number noted is only that of the solvent.

It is important for people administering any vaccination which uses a process of reconstituting a lyophilized vaccine with a separate solvent that they are aware of the risk of accidentally omitting to follow this procedure when the vaccine and solvent are supplied in bulk rather than pre-packaged in pairs.

We would urge vaccine manufacturers and purchasers to consider that the financial savings gained from the bulk packaging of vaccines and solvents could be at the expense of immunization failures resulting in potentially life threatening cases of preventable diseases.

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Appendix 10: The TAPS taxonomy of error reported in general practice

This appendix contains the TAPS taxonomy, which is the result of the work described in this thesis and appears in the paper entitled ‘Patient safety events reported in general practice: a taxonomy’ (Appendix 7) which is in press and was accepted for publication on June 15th 2007 in the journal *Quality and Safety in Health Care*.

The TAPS taxonomy of error reported in general practice (Makeham, Stromer
et al. 2007)

1. Errors related to the Processes of Health Care

1.1. Errors in practice and health care systems

- 1.1.1 Errors relating to incorrect patient identification
 - 1.1.2 Appointments and message handling errors
 - 1.1.3 Patient record and filing system errors
 - 1.1.4 Recall event and recall systems errors
 - 1.1.5 Computer systems errors
 - 1.1.6 Errors in the maintenance of a safe physical environment
 - 1.1.7 Errors in provision of care after hours or inadequate staff coverage
 - 1.1.8 Errors relating to patient confidentiality issues
 - 1.1.9 Practice and health care systems errors not otherwise specified
-

1.2. Investigation errors

- 1.2.1 Errors relating to incorrect patient identification
 - 1.2.2 Errors in the process of requesting investigations
 - 1.2.3 Errors in the process of undertaking investigations
 - 1.2.4 Errors in reporting processes or managing investigation reports
 - 1.2.5 Investigation errors not otherwise specified
-

1.3. Medication errors

- 1.3.1. Electronic prescription writing or medication charting errors
 - 1.3.2 Other prescription or medication charting errors
 - 1.3.3 Medication dispensing and delivery errors
 - 1.3.4 Patient self-administration of medication errors
 - 1.3.5 Medication errors not otherwise specified
-

1.4. Treatment errors (non-medication)

- 1.4.1 Errors in the process of providing Immunisations
 - 1.4.2. Errors in the process of undertaking procedures
 - 1.4.3. Non-medication treatment errors not otherwise specified
-

1.5. Communication errors and process errors not otherwise specified

- 1.5.1. Errors in general communication with patients
 - 1.5.2 Hospital discharge and other hospital based communication errors
 - 1.5.3. Errors in referral to other health care providers
 - 1.5.4 Errors in general communication with other health care providers
 - 1.5.5. Communication and process errors not otherwise specified
-

2. Errors related to the Knowledge and Skills of Health Professionals

2.1. Errors in diagnosis

- 2.1.1. Errors in patient history taking
 - 2.1.2. Errors in patient physical examination
 - 2.1.3. Errors in investigations requested or their interpretation
 - 2.1.4. Diagnosis related errors not otherwise specified
-

2.2. Errors in managing patient care

- 2.2.1 Medication management errors
 - 2.2.2 Knowledge or skills errors in undertaking immunisations
 - 2.2.3 Knowledge or skills errors in undertaking procedures
 - 2.2.4 Errors managing care not otherwise specified
-

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